

HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-K
March 31, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2008

OR

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number 000-24672

HOLLIS-EDEN PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)
4435 Eastgate Mall, Suite 400

13-3697002
(I.R.S. Employer
Identification No.)

San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

Registrant's telephone number, including area code: (858) 587-9333

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class
Common Stock, par value \$0.01 per share

Name of Each Exchange on Which Registered
The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act:

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES NO

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirement for the past 90 days. YES NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. YES NO

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2. (Check One).

Large accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company

Indicate by check mark whether the Registrant is a shell company (as defined in Exchange Act Rule 12b-2). YES NO

The aggregate market value of the voting stock held by nonaffiliates of the Registrant as of June 30, 2008, the end of Hollis-Eden Pharmaceuticals' most recently completed second fiscal quarter, was approximately \$40,770,799 based on the closing stock price of \$1.53 for the Registrant's Common Stock as reported by the Nasdaq Global Market*.

As of March 27, 2009, there were outstanding 29,169,655 shares of the Registrant's Common Stock, \$.01 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of Registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after Registrant's fiscal year end December 31, 2008, are incorporated by reference into Part III of this Annual Report on Form 10-K.

*Excludes the common stock held by executive officers, directors and stockholders whose ownership exceeded 10% of the Registrant's common stock outstanding at June 30, 2008. This calculation does not reflect a determination that such persons are affiliates for any other purposes.

Hollis-Eden Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2008

INDEX

	Page
<u>PART I</u>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	14
Item 1B. <u>Unresolved Staff Comments</u>	23
Item 2. <u>Properties</u>	23
Item 3. <u>Legal Proceedings</u>	23
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	23
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	24
Item 6. <u>Selected Financial Data</u>	26
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	27
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	32
Item 8. <u>Financial Statements and Supplementary Data</u>	33
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	70
Item 9A(T). <u>Controls and Procedures</u>	70
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	72
Item 11. <u>Executive Compensation</u>	72
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters</u>	72
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	73
Item 14. <u>Principal Accountant Fees and Services</u>	73
Item 15. <u>Exhibits and Financial Statement Schedules</u>	74

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, and the information incorporated herein, contains forward-looking statements that involve and are subject to risks and uncertainties. In particular, statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are contained or incorporated by reference in this Annual Report on Form 10-K. We have based these forward-looking statements on our current expectations about future events. While we believe these expectations reflected in this Annual Report on Form 10-K are reasonable, the inclusion of any forward-looking statements should not be regarded as a representation that any of our plans will be achieved and such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Such forward-looking statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words, believe, may, might, can, could, will, would, should, estimate, continue, anticipate, intend, seek, plan, project, expect, or similar expressions. The actual future results for Hollis-Eden Pharmaceuticals, Inc. may differ materially from those discussed here for various reasons, including those discussed in this Annual Report in Part I, Item 1A under the heading Risk Factors, Part II, Item 7 entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Annual Report on Form 10-K. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included in this Annual Report are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements as a result of new information, to reflect future events or developments. When used in this Annual Report, unless otherwise indicated, we, our and us refers to Hollis-Eden Pharmaceuticals, Inc. and its subsidiaries.

PART I

Item 1. Business

GENERAL OVERVIEW

Hollis-Eden Pharmaceuticals, Inc., a development-stage pharmaceutical company, is engaged in the discovery and development of products for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune or metabolic response due to disease or the process of aging. Our current development efforts are primarily focused on a series of adrenal steroid hormones and hormone analogs that are derived from our Hormonal Signaling Technology Platform.

We are currently focused on the development of two clinical drug development candidates TRIOLEX (HE3286), a next-generation compound currently in initial clinical trials for the treatment of type 2 diabetes, ulcerative colitis (UC) and rheumatoid arthritis (RA), and APOPTONE (HE3235), a next-generation compound in a clinical trial for late-stage prostate cancer.

Our research program has also generated new potential clinical leads for further evaluation in preclinical models of different diseases including metabolic and autoimmune conditions, inflammatory diseases of the lung, bone metabolism and regenerative medicine.

Our principal executive offices are located at 4435 Eastgate Mall, Suite 400, San Diego, California 92121, and our telephone number is (858) 587-9333. We are incorporated in Delaware.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Hollis-Eden Pharmaceuticals, HE3286, HE3235, TRIOLEX, APOPTONE, and the Hollis-Eden Pharmaceuticals stylized logo are trademarks of Hollis-Eden Pharmaceuticals, Inc. This filing also includes trademarks owned by other parties. All other trademarks mentioned are the property of their respective owners. Use or display by us of other parties' trademarks or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or product owners.

Our periodic and current reports that we file with the Securities and Exchange Commission, or SEC, are available free of charge, on our website, as soon as reasonably practicable after we have electronically filed them with, or furnished them to, the SEC. Our Internet address is www.holliseden.com. The reference to our website does not constitute incorporation by reference of the information contained on our website.

TECHNOLOGY DESCRIPTION

Hormonal Signaling Technology Platform

Our primary technology development efforts are focused on a series of adrenal steroid hormones and hormone analogs that we believe may be useful in treating a wide variety of medical conditions if successfully developed. These adrenal hormones are known to be depleted as we age, and this process can be accelerated as a result of infectious diseases and other chronic immune system disorders.

Inflammation

One of our primary focus areas for compounds developed from our technology platform is in the area of inflammation. The role of inflammation in disease pathogenesis has become increasingly recognized by the medical community. Chronic inflammation is generally believed to be caused by an over-stimulation of certain components of the immune system, such as reactive oxygen species and pro-inflammatory mediators, due to persistent low-grade infections or the body's inability to differentiate between certain cells or tissues in the body and foreign pathogens. Published studies have implicated chronic inflammation in a host of diseases ranging from autoimmune conditions, such as arthritis and psoriasis, to infectious diseases, including human immunodeficiency virus (HIV), malaria and tuberculosis, and to metabolic disease, including diabetes and cardiovascular disease as well as a number of different cancer types.

One of the most widely used classes of agent for treating inflammation is the corticosteroid class. Industry market research indicates that there are tens of millions of new prescriptions for corticosteroids issued by physicians in the U.S. each year for a wide range of conditions. While these drugs are very potent anti-inflammatory agents, their chronic use can lead to immune suppression and other side effects including bone loss.

Over the last decade, a number of new agents for treating inflammation have been introduced that are focused on inhibiting a specific component of the inflammatory cascade, such as agents that block specific inflammatory cytokines, including TNF-alpha and IL-1 beta, as well as drugs that inhibit specific enzymes, such as COX-2. These drugs have shown impressive activity in a number of clinical conditions such as arthritis, inflammatory bowel disease and psoriasis. However, by focusing on a specific mediator, these agents may not be able to overcome the redundancy built into the immune system and can also cause immune suppression and other side effects in certain patient populations. In addition, the cost of producing a number of these new agents is quite high.

Our goal is to develop compounds that may help regulate a broad array of inflammatory mediators and potentially either maintain or boost a variety of immune responses in conditions of immune suppression, including innate and adaptive cell-mediated immunity.

Innate and Cell-Mediated Immunity

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Humans have three lines of defense against infection. The physical barrier of our skin and mucosal surfaces provides our first line of defense. This effectively protects us from numerous pathogens found in our immediate surroundings. Should a microbe gain entry through a break in the skin, by ingestion or by other means, protection comes from the next two lines of defense innate and adaptive immunity.

Innate immunity refers to the all-purpose, immediate antimicrobial response that occurs regardless of the nature of the invader. For example, macrophages, granulocytes and natural killer cells roam our body and recognize and destroy foreign cells they encounter. This response serves to fight the infection after initial exposure, pending development of adaptive immunity.

The adaptive immune system mounts a highly sophisticated and specialized immune response to protect us against specific invaders, and provides long-term protection or immunity from subsequent exposure to those invaders. Adaptive immunity can be divided into two branches, the cellular or cell-mediated immune response, also known as Th1-type response, and the humoral immune response, also known as Th2-type response. These two interconnected immune functions work in concert through finely tuned checks and balances to mount an appropriate defense. In response to an intracellular pathogen, B-cells of the humoral arm (Th2) proliferate and produce large amounts of appropriate antibodies that flag invaders for elimination from the body. The cellular (Th1) immune response employs specialized T-cells to recognize and destroy host cells showing signs of infection by intracellular pathogens. The relative mobilization of each branch of the immune system depends on the specific disease or condition, and the nature of the response can be influenced by the pathogen itself and where it enters the body.

The balance between the cellular (Th1) and humoral (Th2) arms of the immune system is modulated by a highly integrated network of molecular and cellular interactions driven by cytokines. Cytokines are small proteins that act as intercellular chemical messengers. These cytokines, which are regulated by hormones generated by the endocrine system, can be classified as either Th1 or Th2 depending on their role. Th1 cytokines such as interleukin 2 (IL-2), interferon gamma (IFN-gamma) and interleukin 12 (IL-12) stimulate the cellular response and suppress the humoral response. Th2 cytokines, such as interleukin 10 (IL-10), interleukin 6 (IL-6) and interleukin 4 (IL-4), stimulate the humoral response and suppress the cellular response.

Generally, in healthy individuals the immune system is in homeostasis, or has balanced expression of Th1 and Th2 cytokines. If a foreign invader triggers an adaptive cellular or Th1-type response, the feedback mechanism within the immune system greatly reduces the humoral or Th2-type response. Once the invader is controlled or eliminated, a combination of hormones and cytokines act quickly to return the system to homeostasis through the same feedback mechanism.

Our development strategy is based on the observation that this complicated balance of cytokines is regulated by competing levels of certain adrenal hormones. We believe in young, healthy adults, that the balance between corticosteroids such as cortisol, which have immunosuppressive properties, and compounds we are developing may be an important determinant in whether appropriate levels of cytokines are produced to properly regulate immune responses. As we age, and under conditions of stress, chronic infections or systemic inflammation, levels of these compounds that we believe may counteract the immunosuppressive effect of corticosteroids fall significantly, possibly leading to a decline in the ability to fight off infections that would otherwise be contained by a well functioning immune system.

Hollis-Eden's Approach

With the advent of the technology revolution over the last several decades, scientists have been presented with a whole new series of tools that allow them to study very specific aspects of biological function. This led to a scientific approach that largely centered on how a certain drug might interact with a specific signaling function or target for a specific disease. While this approach has resulted in a number of successful drugs, frequently these compounds are not as effective in clinical practice as anticipated and produce a number of unintended side effects due to the complexity of interactions amongst different systems in human biology.

The research community has increasingly begun to embrace the concept of a systems biology approach to drug development one that accounts for the complexity of interactions between cellular pathways. This approach recognizes that enhancing or inhibiting just one signal in this complicated cascade of events is likely to be too simplistic an approach to overcome many of the more intractable health problems facing medicine today.

Researchers in this emerging field are attempting to integrate a number of different scientific disciplines, such as molecular biology, high speed computing and engineering, to understand these intricate interactions in immune and metabolic function and the dysregulation in these pathways that can lead to a very diverse set of diseases and conditions at an upstream level. The concept is that there may be common links between diseases such as arthritis, diabetes, HIV, Alzheimer's disease and cancer that can all benefit from an appropriate upstream re-regulation of immune and/or metabolic function.

While most researchers in this area are taking a *ground up* approach to understanding each specific component in these intricate cascades and how they relate to one another, and then trying to design drugs that can successfully intervene in correcting dysregulation across all of these pathways, our approach is more *top down*: identify the hormones that we believe have been developed through millions of years of evolution to be the master signalers involved in initiating these cascades and look at conditions where their modulation is dysregulated. By then applying the latest tools of pharmaceutical development, our goal is to design compounds and routes of administration that may deliver these signals when and where they are needed with the goal of intervening in this systemic dysregulation.

As factors such as chronic inflammation, innate and adaptive immunity, and metabolic function are implicated in a host of diseases, including virtually all diseases of aging, we believe successfully applying this approach may have potential utility for a number of important pharmaceutical markets.

DRUG CANDIDATES IN DEVELOPMENT

We are currently focusing our development activities on two compounds from our proprietary series. Our lead clinical drug development candidates are TRIOLEX (HE3286), a next-generation compound currently in clinical trials for the treatment of type 2 diabetes, ulcerative colitis and rheumatoid arthritis, and APOPTONE (HE3235), a next-generation compound in a clinical trial for late-stage prostate cancer.

Each of these compounds is described in more detail below. In addition, our research program, focused on adrenal hormones, has identified additional potential clinical candidates for a wide range of medical conditions.

TRIOLEX (HE3286)

Type 2 Diabetes

Diabetes is a disease in which the body does not produce adequate quantities of, or properly use, insulin. Insulin is a hormone needed to carry glucose from the blood into cells, where it is converted to energy the cells need to perform properly. When insulin is not present in sufficient quantity or does not function correctly, the result is high levels of glucose in the blood. Over time, chronically elevated blood glucose can lead to a host of severe medical conditions including nerve disease, blindness, limb amputation, heart attack, stroke and death. There are two forms of diabetes: type 1, a chronic condition in which the pancreas produces little or no insulin diabetes and type 2, a condition in which the body becomes resistant to the effects of insulin or the body produces some, but not enough, insulin to maintain a normal blood sugar level.

TRIOLEX is a next-generation compound that we are developing for the treatment of type 2 diabetes. We believe that TRIOLEX, which was discovered by our scientists in a pharmaceutical development program targeting metabolism, may be the first in a new class of insulin sensitizers. With TRIOLEX, Hollis-Eden is taking an anti-inflammatory approach to improving insulin sensitivity in patients with type 2

diabetes. Academic researchers have increasingly linked chronic obesity induced inflammation with type 2 diabetes and the potential role of inflammation in promoting insulin resistance in type 2 diabetes is described in the scientific literature.

In the setting of type 2 diabetes, we believe that the mechanism of action for TRIOLEX may be the regulation of the NF-kappaB pathway and other proinflammatory pathways, particularly when these are stimulated through the TLR4 receptor. TLR4 is a receptor expressed on the cell surface of macrophages and

other cells that is stimulated by certain pathogens such as bacteria and viruses or certain chemicals such as dietary fatty acids. Upon stimulation of the TLR4 receptor, a cascade of proinflammatory kinases that include IKK, JNK and p38 is activated, setting off a complex network of signaling pathways, which culminate with the activation of NF-kappaB and a number of genes involved in the inflammatory and cell stress response. Based on preclinical experiments conducted to date, we believe TRIOLEX acts independently of the PPAR-gamma pathway targeted by other insulin sensitizers and appears to down regulate proinflammatory kinases JNK, IKK and p38, which have been associated with impairment of the insulin receptor substrate-1 protein (IRS-1) function, an important cellular mediator of insulin signaling, ultimately causing inappropriate insulin action.

A single-dose Phase I clinical trial conducted during 2007 demonstrated that the compound is orally bioavailable in humans, with significant drug concentrations detected in the blood at the lowest dose tested. The findings also showed that all doses of TRIOLEX tested appear to be safe and well tolerated in healthy volunteers with no reported drug related adverse side effects to date. An on-going Phase I/II double-blind, placebo-controlled, dose ranging clinical trial with TRIOLEX in obese insulin resistant subjects is evaluating the safety, tolerance and pharmacokinetics of TRIOLEX (5mg once daily, 5mg twice daily and 10mg twice daily) when administered for 28 days to obese adult subjects and assessing potential activity of TRIOLEX to decrease insulin resistance. In addition, an open-label cohort of six patients with type II diabetes mellitus will be treated at 10 mg (5 mg BID) for 28 days.

During 2008, Hollis-Eden initiated a Phase II clinical trial with TRIOLEX in type 2 diabetes patients. This Phase II, double-blinded placebo controlled 12-week dosing trial has enrolled over 90 patients with a hemoglobin A1c (HbA1c) level in excess of 7.5 percent who are on a stable dose of metformin only, the current first-line therapy for type 2 diabetes. The primary objectives of this trial are to evaluate the change in HbA1c from baseline to week 12 in the HE3286 treated group when compared to the placebo group and to evaluate the safety and tolerance of HE3286 10 mg per day (5 mg BID) compared to placebo from baseline to week 12.

We have completed three interim analyses of data from this on-going Phase II clinical trial with TRIOLEX in type 2 diabetes patients. The first interim analysis, which we planned pursuant to the study protocol when 25 percent of the subjects reached study-day 57, was completed in December 2008. The second interim analysis was completed in January 2009 and then expanded in January 2009. The third interim analysis was completed in February 2009. Each interim analysis determined that, as of the date of such analysis, TRIOLEX was failing to meet its primary endpoint of lowering HbA1c in subjects treated with TRIOLEX compared to subjects treated with placebo. Each of these three interim analyses showed a statistically significant reversal in favor of placebo over TRIOLEX at day 57. The second interim analysis also showed a statistically significant reversal in favor of placebo over TRIOLEX at day 84 while the third interim analysis showed a trend in favor of placebo over TRIOLEX at day 84. Beginning with the first interim analysis, each of these interim analyses indicate that this trial will not achieve its primary endpoint of a statistically significant reduction in HbA1c at the conclusion of the trial for the total patient population. There were no safety related concerns identified in the interim analyses.

Enrollment in the trial is complete with 95 subjects. All subjects have completed dosing and we expect that the trial should be completed in the second quarter of 2009. We are evaluating all available data and will analyze the results from this study prior to determining the future development strategy for TRIOLEX in type 2 diabetes.

There are several pharmaceutical approaches to treating type 2 diabetes. These include drugs designed to increase insulin production by the pancreas, drugs designed to reduce glucose production by the liver and drugs, referred to as insulin sensitizers, designed to increase the body's sensitivity to insulin, thereby improving glucose disposal from the bloodstream. Frequently clinicians will combine drugs from these different approaches in an effort to achieve appropriate glucose control.

The only currently approved anti-diabetic agents that are known to act as insulin sensitizers are the glitazone class of drugs, which collectively represent 48% of the annual sales in the approximately \$11 billion per year global oral anti-diabetic market. Glitazones appear to act primarily through the activation of a nuclear hormone

receptor, known as PPAR-gamma. While these agents can lower blood glucose, they have been associated with undesirable side effects such as weight gain, edema and increased cardiovascular events. Preclinical studies with TRIOLEX to date indicate that it does not act on the PPAR-gamma receptor which we believe may potentially allow TRIOLEX to avoid the undesirable side effect of weight gain seen with the glitazone class of insulin sensitizers.

The need for new classes of agents to treat type 2 diabetes is significant. There are over 20 million Americans with type 2 diabetes and over 160 million type 2 diabetics worldwide. These figures are increasing rapidly as a result of the aging population and the rising incidence of obesity, which is a common risk factor for the disease. Clinical data indicate only 36% of type 2 diabetics are currently able to achieve the American Diabetes Association maximum recommended HbA1c glucose level of 7.0. Large clinical studies have shown that failure to achieve these glucose targets can progressively lead to severe health consequences including neuropathy, blindness, amputation, heart attack, stroke and death.

Ulcerative Colitis

Based upon the results our scientists observed with TRIOLEX in preclinical models widely used by the pharmaceutical industry and academia to test agents as potential treatments for ulcerative colitis, in 2008 we commenced a Phase I/II clinical trial with TRIOLEX in ulcerative colitis. This Phase I/II dose ranging study will evaluate the safety, tolerance, pharmacokinetics and activity of TRIOLEX when administered orally for 28 days to patients with active, mild-to-moderate ulcerative colitis.

Ulcerative colitis is a chronic inflammation of the large intestine, or colon, and is related to another condition of inflammation of the intestines called Crohn's disease. Ulcerative colitis and Crohn's disease are frequently referred to together as inflammatory bowel disease, or IBD. Ulcerative colitis and Crohn's disease together affect approximately 500,000 to 2 million people in the United States.

Rheumatoid Arthritis

Based upon the results our scientists observed in preclinical collagen induced arthritis models, as well as a preclinical model of collagen antibody induced arthritis, in 2008 Hollis-Eden initiated a Phase I/II clinical trial with TRIOLEX for the treatment of rheumatoid arthritis. The 28-day oral dose ranging study is assessing safety and pharmacokinetics in stable rheumatoid arthritis patients on methotrexate only.

Our scientists believe potential mechanisms of action for TRIOLEX may involve regulation of the NF-kappaB pathway. NF-kappaB is a transcription factor that controls genes whose products are involved in the inflammatory signaling pathway, including TNF-alpha and IL-6. These cytokines are thought to be involved in the pathogenesis of certain autoimmune diseases such as ulcerative colitis and rheumatoid arthritis, and are also implicated in the pathogenesis of metabolic diseases, cardiovascular disorders, cancer and in general, diseases associated with aging.

Rheumatoid arthritis is a type of chronic arthritis that occurs in joints on both sides of the body (such as hands, wrists or knees). In rheumatoid arthritis, the immune system attacks the joints and sometimes the other organs. Rheumatoid arthritis affects more than 1.3 million people in the United States. Annual sales in the United States of drugs to treat rheumatoid arthritis are expected to reach \$14 billion by 2009, driven by the increase in the aging population and the use of new expensive biological treatments.

Pulmonary Diseases and other Autoimmune Diseases

We are also interested in exploring the potential for TRIOLEX and other new compounds from our technology platform in a variety of pulmonary diseases including, cystic fibrosis, chronic pulmonary disease and asthma as well as other autoimmune indications.

APOPTONE (HE3235)

Prostate Cancer

APOPTONE is a second-generation compound we have selected for clinical development in the area of hormone-driven cancers, such as prostate cancer. Approximately 234,000 patients are diagnosed each year with prostate cancer, and global sales for leading prostate cancer drugs range approximately from \$500 million to \$1.8 billion annually. In 2008, we initiated a Phase I/II clinical trial with APOPTONE in late-stage prostate cancer patients who have failed hormone therapy and at least one round of chemotherapy treatment.

The Phase I/II open-label dose ranging clinical trial, being conducted with the Prostate Cancer Clinical Trial Consortium (PCCTC), is evaluating the safety, tolerance, pharmacokinetics and potential activity of APOPTONE when administered twice daily in late-stage prostate cancer patients. Potential activity of the compound will be measured by effect on well-established markers of progression free survival (PFS), as determined by standard prostate-specific antigen (PSA) tests, computerized tomography (CT), magnetic resonance imaging (MRI), or bone scan, and effect on circulating tumor cells (CTC).

APOPTONE has been tested in a number of preclinical cancer models and has shown indications of activity to date in controlling the incidence, growth and development of new tumors in these models. We believe that APOPTONE may be directly inducing apoptosis, or cell death, in tumor cells, as opposed to traditional hormone blockade therapies directed at simply interrupting either the synthesis or the signaling of the tumor cell growth through the androgen or estrogen receptor. While hormone blockade therapy can effectively control prostate cancer for a period of time, it will eventually fail and the cancer can continue to grow and spread.

In addition to prostate cancer, we are exploring the potential of APOPTONE in other cancers such as breast cancer.

Competition

Given the large market opportunities for products that treat the indications for which we are currently developing our compounds, most major pharmaceutical companies and many biotechnology companies have programs directed toward finding drugs to treat indications we are exploring and the competition in these markets is intense. In metabolism and type 2 diabetes, there are a number of drugs such as Actos[®] from Takeda Pharmaceuticals and Avandia[®] from GlaxoSmithKline already approved for improving insulin sensitivity, and additional drugs are in development. While Actos[®] and Avandia[®] currently account for a significant share of the market for type 2 diabetes drugs, they are known to cause the unwanted side effects of weight gain and edema. In addition, both have been given black box warnings by the FDA for heart failure related to drug treatment.

In the area of immune modulators for correcting immune dysregulation, a number of companies are targeting inhibition or enhancement of a single cytokine or other mediator. For example, Amgen's Enbrel[®] targets TNF-alpha, as does Johnson & Johnson's Remicade[®]. Other immune-modulating drugs such as Celebrex from Pfizer target COX-2. While these targeted approaches have shown clinical benefit and have generated significant sales volumes, redundant mechanisms in the immune system can limit their effectiveness. In addition, side effects and cost issues may limit their global utility. In contrast, we believe our compounds may affect multiple cytokines and inflammatory mediators in a physiologic way that may make them more attractive drug candidates than currently available therapies, assuming they are successfully developed and commercialized.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

In addition, there are also a number of other companies with drug candidates in development targeting late-stage prostate cancer, including compounds already in Phase 3 clinical trials.

Government Regulation

General

The manufacturing and marketing of our proposed drug candidates and our research and development activities are and will continue to be subject to regulation by federal, state and local governmental authorities in the U.S. and other countries. In the U.S., pharmaceuticals are subject to rigorous regulation by the FDA, which reviews and approves the marketing of drugs. The Federal Food, Drug and Cosmetic Act, the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacturing, labeling, storage, record keeping, advertising and promotion of our potential products.

Approval Process

The process of obtaining FDA approval for a new drug may take many years and generally involves the expenditure of substantial resources. The steps required before a new drug can be produced and marketed for human use include clinical trials and the approval of a New Drug Application.

Preclinical Testing. In the preclinical phase of development, the promising compound is subjected to extensive laboratory and animal testing to determine if the compound is biologically active and safe.

Investigational New Drug, or IND. Before human tests can start, the drug sponsor must file an IND application with the FDA, showing how the drug is made and the results of animal testing. IND status allows initiation of clinical investigation within 30 days of filing if the FDA does not respond with questions during the 30-day period.

Human Clinical Testing. The human clinical testing program usually involves three phases which generally are conducted sequentially, but which, particularly in the case of anti-cancer and other life-saving drugs, may overlap or be combined. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND filing. Each clinical study is conducted under the auspices of an independent Institutional Review Board, or IRB, for each institution at which the study will be conducted. The IRB will consider, among other things, all existing pharmacology and toxicology information on the product, ethical factors, the risk to human subjects and the potential benefits of therapy relative to risk.

In Phase I clinical trials, studies usually are conducted on healthy volunteers or, in the case of certain terminal illnesses such as AIDS or cancer, patients with disease that has failed to respond to other treatment, to determine the maximum tolerated dose, side effects and pharmacokinetics of a product. Phase II studies are conducted on a small number of patients having a specific disease to determine initial efficacy in humans for that specific disease, the most effective doses and schedules of administration, and possible adverse effects and safety risks. Phase II/III differs from Phase II in that the trials involved may include more patients and, at the sole discretion of the FDA, be considered the pivotal trials, or trials that will form the basis for FDA approval. Phase III normally involves the pivotal trials of a drug, consisting of wide-scale studies on patients with the same disease, in order to evaluate the overall benefits and risks of the drug for the treated disease compared with other available therapies. The FDA continually reviews the clinical trial plans and results and may suggest design changes or may discontinue the trials at any time if significant safety or other issues arise.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

New Drug Application, or NDA. Upon successful completion of Phase III clinical trials, the drug sponsor files an NDA with the FDA for approval containing all information that has been gathered. The NDA must include the chemical composition of the drug, scientific rationale, purpose, animal and laboratory studies, results of human tests, formation and production details, and proposed labeling.

Post Approval. If the FDA approves an NDA, the drug sponsor is required to submit reports periodically to the FDA containing adverse reactions, production, quality control and distribution records. The FDA may also

require post-marketing testing to support the conclusion of efficacy and safety of the product, which can involve significant expense. After FDA approval is obtained for initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications.

The testing and approval process is likely to require substantial time and effort, and there can be no assurance that any FDA approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the side effects of the drug (safety) and its therapeutic benefits (efficacy). Additional preclinical or clinical trials may be required during the FDA review period and may delay marketing approval. The FDA may also deny an NDA if applicable regulatory criteria are not met.

Outside the U.S., we will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for our products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements vary widely from country to country.

Manufacturing

We do not have, and do not intend to establish, manufacturing facilities to produce our drug candidates or any future products. We plan to control our capital expenditures by using contract manufacturers to make our products. We believe that there are a sufficient number of high-quality FDA-approved contract manufacturers available, and we have had discussions and in some cases established relationships to fulfill our near-term production needs for both clinical and commercial use.

The manufacture of our drug candidates or any future products, whether done by outside contractors as planned or internally, will be subject to rigorous regulations, including the need to comply with the FDA's current Good Manufacturing Practice standards. As part of obtaining FDA approval for each product, each of the manufacturing facilities must be inspected, approved by and registered with the FDA. In addition to obtaining FDA approval of the prospective manufacturer's quality control and manufacturing procedures, domestic and foreign manufacturing facilities are subject to periodic inspection by the FDA and/or foreign regulatory authorities.

Patents

We currently own or have obtained licenses to a number of U.S. and foreign patents and patent applications. We consider the protection of our technology, whether owned or licensed, to the exclusion of use by others, to be vital to our business. While we intend to focus primarily on patented or patentable technology, we may also rely on trade secrets, unpatented property, know-how, regulatory exclusivity, patent extensions and continuing technological innovation to develop our competitive position. In the U.S. and certain foreign countries, the exclusivity period provided by patents covering pharmaceutical products may be extended by a portion of the time required to obtain regulatory approval for a product.

In certain countries, some pharmaceutical-related technology such as disease treatment methods are not patentable or only recently have become patentable, and enforcement of intellectual property rights in many countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many countries can be expected to be problematic or unpredictable. We cannot guarantee that any patents issued or licensed to us will provide us with competitive advantages or will not be challenged by others. Furthermore, we cannot be certain that others will not independently develop similar products or will not design around patents issued or licensed to us.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

In most cases, patent applications in the U.S. are maintained in secrecy until 18 months after the earliest filing or priority date. Publication of discoveries in the scientific or patent literature, if made, tends to lag behind actual discoveries by at least several months. U.S. patent applicants can elect to prevent publication until the application issues by agreeing not to file the application outside the U.S. This option is rarely used for pharmaceutical patent applications. Consequently, we cannot be certain that a licensor of its intellectual property

was the first to invent certain technology or compounds covered by pending patent applications or issued patents or that it was the first to file patent applications for such inventions. In addition, the patent positions of biotechnology and pharmaceutical companies, including our own, are generally uncertain, partly because they involve complex legal and factual questions.

In addition to the considerations discussed above, companies that obtain patents claiming products, uses or processes that are necessary for, or useful to, the development of our drug candidates or future products could bring legal actions against us claiming infringement. Patent litigation is typically costly and time consuming, and if such an action were brought against us, it could result in significant cost and diversion of our attention. We may be required to obtain licenses to other patents or proprietary rights, and we cannot guarantee that licenses would be made available on terms acceptable to us. If we do not obtain such licenses, we could encounter delays in product market introductions while we attempt to develop or license technology designed around such patents, or we could find that the development, manufacture or sale of products requiring such licenses is foreclosed.

Further, we cannot guarantee that patents that are issued will not be challenged, invalidated or infringed upon or designed around by others, or that the claims contained in such patents will not infringe the patent claims of others, or provide us with significant protection against competitive products, or otherwise be commercially valuable. To the extent that we are unable to obtain patent protection for our products or technology, our business may be materially adversely affected by competitors who develop substantially equivalent technology.

Technology Agreements

In August 2002, we entered into a Sublicense Agreement with Pharmadigm, Inc. (currently known as Inflabloc Pharmaceuticals, Inc.). Under the agreement, we obtained exclusive worldwide rights to certain intellectual property of Pharmadigm and the University of Utah and we agreed to make aggregate payments of \$0.9 million in cash or in shares of our common stock, at our option, over the next year. We elected to make such payments in equity and have issued a total of 168,921 shares of our common stock in complete satisfaction of this requirement. We will also make additional milestone and royalty payments to Pharmadigm if we meet specified development and commercialization milestones for products covered by the patents. No such milestones have been met to date. The principal patents licensed under the agreement, originally licensed to Pharmadigm from the University of Utah, relate to inventions by Dr. Raymond Daynes and Dr. Barbara A. Areneo. Dr. Daynes served as a scientific consultant for us from 1999 to mid-2003.

In October 2000, we acquired a 21% equity stake in Aeson Therapeutics Inc. (Aeson) and an exclusive worldwide sublicense to three issued patents in the area of adrenal steroids in exchange for \$2.0 million in cash and 208,672 shares of our common stock valued at \$2 million. As part of the transaction, Aeson and its stockholders granted us an exclusive option to acquire the remainder of Aeson at a predetermined price. In March 2002, we amended certain aspects of our agreements with Aeson. Under the amendments, we paid Aeson \$1.2 million, which extended the initial date by which we could exercise our option to acquire the remainder of Aeson to September 30, 2002. We also received additional equity securities of Aeson as a result of this payment. We elected not to exercise the option to acquire the remainder of Aeson by September 30, 2002. On June 7, 2006, we acquired substantially all of the assets of Aeson. As consideration for Aeson's assets, we agreed (i) to issue a total of 35,000 shares of our common stock to Aeson at the closing of the acquisition and (ii) to issue to Aeson's stockholders up to a total of 165,000 additional shares of our common stock if certain development milestones are achieved. We have not achieved any of the development milestones to date.

Employees

As of March 27, 2009, we had 42 full-time, non-union employees. We believe that our relations with our employees are good.

Executive Officers and Senior Management

Our executive officers and senior management and their ages as of March 27, 2009 are as follows:

Name	Age	Position
James M. Frincke, Ph.D.	58	Interim Chief Executive Officer
Robert L. Marsella	56	Senior Vice President, Business Development and Marketing
Christopher L. Reading, Ph.D.	61	Chief Scientific Officer
Dwight R. Stickney, M.D.	66	Chief Medical Officer
Robert W. Weber	58	Interim Chief Financial Officer, Chief Accounting Officer and Vice President, Operations

James M. Frincke, Ph.D. joined Hollis-Eden as Vice President, Research and Development in November 1997, was promoted to Executive Vice President in March 1999, to Chief Scientific Officer in December 2001, to Chief Operating Officer in February 2008 and to Interim Chief Executive Officer on March 18, 2009. Dr. Frincke joined Hollis-Eden from ProInx, Inc., where he served as Vice President, Therapeutics Research and Development from 1995 to 1997. During his 28 years in the biotechnology industry, Dr. Frincke has managed major development programs including drugs, biologicals, and cellular and gene therapy products aimed at the treatment of cancer, infectious diseases and organ transplantation. Since joining the biotechnology industry, Dr. Frincke has held vice president, research and development positions in top tier biotechnology companies including Hybritech/Eli Lilly and SyStemix Inc. (acquired by Novartis). In various capacities, he has been responsible for all aspects of pharmaceutical development including early stage research programs, product evaluation, pharmacology, manufacturing, and the management of regulatory and clinical matters for lead product opportunities. Dr. Frincke has authored or co-authored more than 100 scientific articles, abstracts and regulatory filings. Dr. Frincke received his B.S. in Chemistry and his Ph.D. in Chemistry from the University of California, Davis. Dr. Frincke completed his postdoctoral work at the University of California, San Diego.

Robert L. Marsella became Vice President of Business Development and Marketing of Hollis-Eden in September 1997, and was promoted to Senior Vice President of Business Development and Marketing in December 2004. Mr. Marsella has more than 27 years of senior management, marketing, and distribution experience. Prior to joining Hollis-Eden, Mr. Marsella acted as a distributor of various cardiac related hospital products for a number of years. In addition, he has also served as Regional Manager for Genentech and launched ActivaseTM, t-pa (a biopharmaceutical drug) in the Western United States. Prior to joining Genentech, Mr. Marsella marketed intravenous infusion pumps for Imed Corporation a division of Warner Lambert for a number of years. Mr. Marsella began his career as a field sales representative and soon after was promoted to regional sales manager for U.S. Surgical Corporation, Auto Suture division. Mr. Marsella received his B.A. degree from San Diego State University.

Christopher L. Reading, Ph.D. became Vice President of Scientific Development in January 1999, was promoted to Executive Vice President, Scientific Development in March 2002 and to Chief Scientific Officer in February 2008. Prior to joining Hollis-Eden, Dr. Reading was Vice President of Product and Process Development at Novartis Inc.-owned SyStemix Inc. During this time, he successfully filed three investigational new drug applications (INDs) in the areas of stem cell therapy technology and stem cell gene therapy for HIV/AIDS. Prior to joining SyStemix, Dr. Reading served on the faculty of the M.D. Anderson Cancer Center in Houston for nearly 13 years. His positions there included Associate and Assistant Professor of Medicine in the Departments of Hematology and Tumor Biology. During his career, Dr. Reading has given more than 25 national and international scientific presentations, published more than 50 peer-reviewed journal articles and 15 invited journal articles as well as written nearly 20 book chapters, and received numerous grants and contracts which supported his research activities. Dr. Reading has served on the National Science Foundation Advisory Committee for Small Business Innovative Research Grants (SBIR) as well as on the editorial boards of *Journal of Biological Response Modifiers* and *Molecular Biotherapy*. He holds a number of patents for his work with monoclonal antibodies and devices. Dr. Reading received his Ph.D. in Biochemistry at the University of

California at Berkeley and completed postdoctoral study in tumor biology at The University of California at Irvine. He earned his B.A. in cell biology at the University of California at San Diego.

Dwight R. Stickney, M.D. joined Hollis-Eden as Medical Director, Oncology in May 2000, was appointed Vice President, Medical Affairs in March 2003 and was promoted to Chief Medical Officer in February 2008. Dr. Stickney joined Hollis-Eden from the Radiation Oncology Division of Radiological Associates of Sacramento Medical Group, Inc., in Sacramento, California, where he served as an oncologist since 1993. While at Radiological Associates, he served as Chairman of the Radiation Oncology Division from 1997 to 1999 and was a member of the Radiation Study section of the National Institute of Health's Division of Research Grants from 1993 to 1997. He also served as the Director of Radiation Research for Scripps Clinic and Research Foundation in La Jolla, California. Dr. Stickney has taught in medical academia as Associate Professor of Radiation Medicine at Loma Linda University School of Medicine and has served as Director of the International Order of Forrester's Cancer Research Laboratory and on the Board of Directors of the California Division of the American Cancer Society. Earlier in his career, Dr. Stickney held positions with Burroughs Wellcome and the Centers for Disease Control, and academic teaching appointments at The University of California at Los Angeles and The University of California at Riverside. He has also served as a consultant for a number of biotechnology companies on the design and conduct of clinical trials. Dr. Stickney holds a Bachelor of Science in Microbiology, a Masters of Science in Immunology, and a M.D. from Ohio State University. In addition, he is certified as a Diplomat of the American Board of Internal Medicine and Hematology and a Diplomat of the American Board of Radiology, Therapeutic Radiology.

Robert W. Weber joined Hollis-Eden in March 1996 and currently serves as the Interim Chief Financial Officer and Chief Accounting Officer and was promoted to Vice President Operations in February 2008. Mr. Weber has over thirty years of experience in financial management. He has been employed at executive levels by multiple start-up companies and contributed to the success of several turnaround situations. He previously served as Vice President of Finance at Prometheus Products, a subsidiary of Sierra Semiconductor (now PMC Sierra), from 1994 to 1996, and Vice President Finance and Chief Financial Officer for Amercom, a personal computer telecommunications software publishing company, from 1993 to 1994. From February 1988 to August 1993, Mr. Weber served as Vice President Finance and Chief Financial Officer of Instromedix, a company that develops and markets medical devices and software. Mr. Weber brings a broad and expert knowledge of many aspects of financial management. In various capacities, he has been responsible for all aspects of finance and accounting including cost accounting, cash management, SEC filings, treasury, investor relations, private and venture financing, corporate legal matters, acquisitions/divestitures as well as information technology, human resources and facilities. Mr. Weber received a B.S. from GMI Institute of Technology (now Kettering University) and a MBA from the Stanford Graduate School of Business.

Item 1A. Risk Factors

In evaluating our business, you should consider the following discussion of risks, in addition to other information contained in this Annual Report on Form 10-K, as well as our other public filings with the Securities and Exchange Commission. Any of the following risks could materially adversely affect our business, financial condition, results of operations and prospects.

If we do not obtain government regulatory approval for our drug candidates, we will be unable sell products and we will not generate revenues.

Our principal development efforts are currently centered around a proprietary class of small compounds which we believe shows promise for the treatment of several diseases and disorders. However, all drug candidates require approval by the FDA before they can be commercialized in the United States as well as approval by various foreign government agencies before they can be commercialized in other countries. These regulations change from time to time and new regulations may be adopted. None of our drug candidates have been approved for commercial sale and we do not expect that any of our present or future drug candidates will be

commercially available for a number of years, if at all. We have incurred losses since our inception and we expect to continue to incur significant additional operating losses for the foreseeable future as we fund development, preclinical and clinical testing and other expenses in support of regulatory approval of our drug candidates. While limited clinical trials of our drug candidates have been conducted to date, significant additional trials are required, and we may not be able to demonstrate that our drug candidates are safe or effective. In addition, success in early development does not mean that later development will be successful because, for example, drug candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical testing. For example, the Company has completed three interim analyses of data from our on-going Phase II clinical trial with TRIOLEX in type 2 diabetes patients and each interim analysis determined that, as of the date of such analysis, TRIOLEX was failing to meet its primary endpoint of lowering HbA1c in subjects treated with TRIOLEX compared to subjects treated with placebo. Each of these three interim analyses showed a statistically significant reversal in favor of placebo over TRIOLEX at day 57. The second interim analysis also showed a statistically significant reversal in favor of placebo over TRIOLEX at day 84 while the third interim analysis showed a trend in favor of placebo over TRIOLEX at day 84. Beginning with the first interim analysis, each of these interim analyses indicate that this trial will not achieve its primary endpoint of a statistically significant reduction in HbA1c at the conclusion of the trial for the total patient population. Our clinical experience with our drug candidates is limited, and to date our drug candidates have been tested in less than the number of patients that will likely need to be studied to gain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these drug candidates. In addition, we do not know whether early results from any of our ongoing clinical trials will be predictive of final results of any such trial. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval and we will experience potentially significant delays in, or be required to abandon, development of the drug candidate. If we do not receive FDA or foreign approvals for our drug candidates, we will not be able to sell products and will not generate revenues. If we receive regulatory approval of one of our drug candidates, such approval may impose limitations on the indicated uses for which we may market the resulting product, which may limit our ability to generate significant revenues. Further, U.S. or foreign regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain approval of our drug candidates or require significant additional costs to obtain such approvals. In addition, if regulatory authorities determine that we or a partner conducting research and development activities on our behalf have not complied with regulations in the research and development of one of our drug candidates, then they may not approve the drug candidate and we will not be able to market and sell it. If we were unable to market and sell our drug candidates, our business and results of operations would be materially and adversely affected.

Recent publicity concerning the safety of certain drug products has resulted in heightened scrutiny by the FDA in the process of approving new drugs, which could delay or limit any regulatory approvals we may obtain for our drug candidates.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention

to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials by drug development companies. As a result, the FDA may require us to conduct additional preclinical studies or clinical trials during the clinical development of one or more of our drug candidates as a condition precedent to approval which could potentially delay our development plans, limit the indications for which our drug candidates are ultimately approved, and otherwise adversely impact us.

If we do not successfully commercialize our drug candidates, we may never achieve profitability.

We have experienced significant operating losses to date because of the substantial expenses we have incurred to acquire and fund development of our drug candidates. We have never had significant operating revenues and have never commercially introduced a product. Our accumulated deficit was approximately \$236.2 million as of December 31, 2008. Our net losses for fiscal years 2008, 2007 and 2006 were approximately \$21.6 million, \$23.1 million and \$30.2 million, respectively. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even if we were ultimately to receive regulatory approval for one or more of our drug candidates, we may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost effectiveness, the cost of manufacturing the product on a commercial scale, the effect of competition with other drugs, or because we may have inadequate financial or other resources to pursue one or more of our drug candidates through commercialization. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

As a result of our intensely competitive industry, we may not gain enough market share to be profitable.

The biotechnology and pharmaceutical industries are intensely competitive. We have numerous competitors in the U.S. and elsewhere. Because we are pursuing potentially large markets, our competitors include major multinational pharmaceutical companies, specialized biotechnology firms as well as from academic institutions, government agencies and private and public research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our drug candidates, assuming that our drug candidates gain regulatory approval. A large number of companies including Merck & Company, Inc., GlaxoSmithKline, Takeda Pharmaceuticals, Amylin Pharmaceuticals, Inc., AstraZeneca, Novartis, Novo Nordisk, Pfizer, Sanofi-Aventis and Eli Lilly and Co. are developing and marketing new drugs for the treatment of type 2 diabetes. Similarly, a large number of companies, including Merck & Company, Inc., Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc., are developing and marketing new drugs for the treatment of chronic inflammatory conditions. In addition, there are also a number of other companies with drug candidates in development targeting late-stage prostate cancer, including compounds already in Phase 3 clinical trials. One or more such compounds may be approved before any of our drug candidates could potentially be approved. Many, if not all, of these competing drug development programs are being conducted by pharmaceutical and biotechnology companies with considerably greater financial resources, human resources and experience than ours.

Many of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations than we do. In addition, academic and government institutions have become increasingly aware of the commercial value of their research findings. These institutions are now more likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to develop and market commercial products.

Our competitors may succeed in developing or licensing technologies and drugs that are more effective or less costly than any we are developing. Our competitors may succeed in obtaining FDA or other regulatory

approvals for drug candidates before we do. If competing drug candidates prove to be more effective or less costly than our drug candidates, our drug candidates, even if approved for sale, may not be able to compete successfully with our competitors' existing products or new products under development. Similarly, we cannot predict whether any of our drug candidates, if approved, will have sufficient advantages to cause healthcare professionals to adopt our products over competing products. If we are unable to compete successfully, we may never be able to sell enough products at a price sufficient to permit us to generate profits.

We may need to raise additional money before we achieve profitability; if we fail to raise additional money, it could be difficult or impossible to continue our business.

As of December 31, 2008, our cash and cash equivalents totaled approximately \$24.2 million. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements for at least the next 12 months. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We will require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

we may not obtain additional financial resources when necessary or on terms favorable to us, if at all; and

any available additional financing may not be adequate.

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

Failure to protect our proprietary technology could impair our competitive position.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

We own or have obtained a license to a number of U.S. and foreign patents and patent applications. Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to our ability to commercialize our drug candidates, if approved and our ability to operate our business without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes. Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our drug candidates, if

approved, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. Our domestic patent position is also highly uncertain and involves complex legal and factual questions. The applicant or inventors of subject matter covered by patent applications or patents owned by or licensed to us may not have been the first to invent or the first to file patent applications for such inventions. Due to uncertainties regarding patent law and the circumstances surrounding our patent applications, the pending or future patent applications we own or have licensed may not result in the issuance of any patents. Existing or future patents owned by or licensed to us may be challenged, infringed upon, invalidated, found to be unenforceable or circumvented by others. Further, any rights we may have under any issued patents may not provide us with sufficient protection against similar competitive products or technologies that do not infringe our patents or otherwise cover commercially valuable products or processes.

Litigation or other disputes regarding patents and other proprietary rights may be expensive, cause delays in bringing products to market and harm our ability to operate.

The manufacture, use or sale of our drug candidates may infringe on the patent rights of others. If we are unable to avoid infringement of the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming and can preclude, delay or suspend commercialization of our drug candidates. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, or fail to successfully defend an infringement action or have the patents we are alleged to infringe declared invalid, we may

incur substantial money damages;

encounter significant delays in bringing our drug candidates to market;

be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment without first obtaining licenses to do so; and/or

not be able to obtain any required license on favorable terms, if at all.

In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a U.S. patent application or patent, we may decide or be required to participate in interference proceedings in the U.S. Patent and Trademark Office in order to determine the priority of invention. Loss of such an interference proceeding would deprive us of patent protection sought or previously obtained and could prevent us from commercializing our products. Participation in such proceedings could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

Litigation may be expensive and time consuming and may adversely affect our operations.

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Participation in such proceedings is time consuming and could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators and sponsored researchers and other

advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Existing pricing regulations and reimbursement limitations may limit our potential profits from the sale of our products.

The requirements governing product licensing, pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after product-licensing approval is granted. As a result, we may obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that reduce our profits from the sale of the product. In some foreign markets pricing of prescription pharmaceuticals is subject to continuing government control even after initial marketing approval. In addition, certain governments may grant third parties a license to manufacture our product without our permission. Such compulsory licenses may be on terms that are less favorable to us and would likely have the effect of reducing our revenues.

Varying price regulation between countries can lead to inconsistent prices and some re-selling by third parties of products from markets where products are sold at lower prices to markets where those products are sold at higher prices. Any practice of exploiting price differences between countries could undermine our sales in markets with higher prices and reduce the sales of our future products, if any.

While we do not have any applications for regulatory approval of our drug candidates currently pending, any decline in the size of the markets in which we may in the future sell commercial products, assuming our receipt of the requisite regulatory approvals, could cause the perceived market value of our business and the price of our common stock to decline.

Our ability to commercialize our drug candidates successfully also will depend in part on the extent to which reimbursement for the cost of our drug candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Third-party payers are increasingly challenging the prices charged for medical products and services. If we succeed in bringing any of our drug candidates to the market, such drug candidates may not be considered cost effective and reimbursement may not be available or sufficient to allow us to sell such drug candidates on a profitable or competitive basis.

Delays in the conduct or completion of our preclinical or clinical studies or the analysis of the data from our preclinical or clinical studies may result in delays in our planned filings for regulatory approvals, or adversely affect our ability to enter into collaborative arrangements.

The current status of our drug candidates is set forth below. We have either completed or are in the midst of:

Phase I clinical trial with TRIOLEX (HE3286) in the United States under an IND, for the treatment of metabolic diseases;

Phase I/II clinical trial with TRIOLEX (HE3286) in the United States under an IND for the treatment of metabolic diseases;

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Phase II clinical trial with TRIOLEX (HE3286) in the United States in type 2 diabetes patients under an IND for the treatment of metabolic diseases;

Phase I/II clinical trial with TRIOLEX (HE3286) in the United States under an IND for the treatment of ulcerative colitis;

Phase I/II clinical trial with TRIOLEX (HE3286) in the United States in rheumatoid arthritis patients under an IND for the treatment of diseases of inflammation; and

Phase I/II clinical trial with APOPTONE (HE3235) in the United States in late-stage prostate cancer patients who have failed hormone therapy and at least one round of chemotherapy treatment under an IND for the treatment of hormone-sensitive cancers including prostate cancer.

We may encounter problems with some or all of our completed or ongoing studies that may cause us or regulatory authorities to delay or suspend our ongoing studies or delay the analysis of data from our completed or ongoing studies. We rely, in part, on third parties to assist us in managing and monitoring our preclinical and clinical studies. We generally do not have control over the amount and timing of resources that our business partners devote to our drug candidates. Our reliance on these third parties may result in delays in completing or failure to complete studies if third parties fail to perform their obligations to us. If the results of our ongoing and planned studies for our drug candidates are not available when we expect or if we encounter any delay in the analysis of the results of studies of our drug candidates:

we may not have the financial resources to continue research and development of any of our drug candidates;

we may not be able to enter into collaborative arrangements relating to any drug candidate subject to delay in regulatory filing;

we may lose any competitive advantage associated with early market entry; and

our ability to generate revenues may be delayed.

Any of the following reasons, among others, could delay or suspend the completion of our ongoing and future studies:

delays in enrolling volunteers;

interruptions in the manufacturing of our drug candidates or other delays in the delivery of materials required for the conduct of our studies;

lower than anticipated retention rate of volunteers in a clinical trial;

unfavorable efficacy results;

serious side effects experienced by study participants relating to the drug candidate;

reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

failure to conduct a clinical trial in accordance with regulatory requirements or clinical protocols;

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

inspection of a clinical trial operations or clinical trial site by regulatory authorities resulting in the imposition of a clinical hold;

new communications from regulatory agencies about how to conduct these studies; or

failure to raise additional funds resulting in lack of adequate funding to continue a clinical trial or study.

If the manufacturers of our drug candidates do not comply with current Good Manufacturing Practices regulations, or cannot produce sufficient quantities of our drug candidates to enable us to continue our development, we will fall behind on our business objectives.

Manufacturers producing our drug candidates must follow current Good Manufacturing Practices regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to current Good Manufacturing Practices regulations and cannot be brought up to such a standard, we

will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates.

We also rely on our manufacturers to supply us with a sufficient quantity of our drug candidates to conduct clinical trials. If we have difficulty in the future obtaining our required quantity and quality of supply, we could experience significant delays in our development programs and regulatory process.

Our ability to achieve any significant revenue may depend on our ability to establish effective sales and marketing capabilities.

Our efforts to date have focused on the development and evaluation of our drug candidates. As we continue preclinical and clinical studies and seek to commercialize our drug candidates, we may need to build a sales and marketing infrastructure. As a company, we have no experience in the sales and marketing of pharmaceutical products. If we fail to establish a sufficient marketing and sales force or to make alternative arrangements to have our drug candidates marketed and sold by others on attractive terms, it will impair our ability to commercialize our drug candidates and to enter new or existing markets. Our inability to effectively enter these markets would materially and adversely affect our ability to generate significant revenues.

If we were to lose the services of members of our management team, or fail to attract or retain qualified personnel in the future, our business objectives would be more difficult to implement, adversely affecting our operations.

Our ability to successfully implement our business strategy depends upon the continued services of our management team. If we lose the services of one or more of these individuals, replacement could be difficult and may take an extended period of time and could impede significantly the achievement of our business objectives.

We may face product liability claims related to the use or misuse of our drug candidates, which may cause us to incur significant losses.

We are currently exposed to the risk of product liability claims due to administration of our drug candidates in clinical trials, since the use or misuse of our drug candidates during a clinical trial could potentially result in injury or death. If we are able to commercialize our products, we will also be subject to the risk of losses in the future due to product liability claims in the event that the use or misuse of our commercial products results in injury or death. We currently maintain liability insurance on a claims-made basis. Because we cannot predict the magnitude or the number of claims that may be brought against us in the future, we do not know whether the insurance policies' coverage limits are adequate. The insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. Any claims against us, regardless of their merit, could substantially increase our costs and cause us to incur significant losses.

Our securities could be subject to extreme price fluctuations that could adversely affect your investment.

The market prices for securities of life sciences companies, particularly those that are not profitable, are highly volatile. Publicized events and announcements, most of which we cannot control, may have a significant impact on the market price of our common stock, which has been and is likely to continue to be volatile. For example:

biological or medical discoveries by competitors;

public concern about the safety of our drug candidates;

delays in the conduct or analysis of our preclinical or clinical studies;

unfavorable results from preclinical or clinical studies;

delays in obtaining or failure to obtain purchase orders of our drug candidates;

announcements in the scientific and research community;

changes in the potential commercial markets for our drug candidates;

unfavorable developments concerning patents or other proprietary rights;

unfavorable domestic or foreign regulatory or governmental developments or actions;

broader economic, industry and market trends unrelated to our performance;

issuances of new equity securities by us, pursuant to our effective shelf registration statement or otherwise;

discussion of us or our stock price by the financial and scientific press and in online investor communities; or

additions or departures of key personnel

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$0.28 to \$10.25 between September 30, 2005 and March 27, 2009.

These broad market fluctuations may adversely affect the ability of a stockholder to dispose of his shares at a price equal to or above the price at which the shares were purchased. In addition, in the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Any litigation against our company, including this type of litigation, could result in substantial costs and a diversion of management's attention and resources, which could materially adversely affect our business, financial condition and results of operations.

We may be delisted from The Nasdaq Global Market, which could materially limit the trading market for our common stock.

Our common stock is quoted on The Nasdaq Global Market. In order to continue to be included in The Nasdaq Global Market, a company must meet Nasdaq's maintenance criteria. We may not be able to continue to meet these listing criteria. Failure to meet Nasdaq's maintenance criteria may result in the delisting of our common stock from The Nasdaq Global Market. If our common stock is delisted, in order to have our common stock relisted on The Nasdaq Global Market we would be required to meet the criteria for initial listing, which are more stringent than the maintenance criteria. Accordingly, if we were delisted we may not be able to have our common stock relisted on The Nasdaq Global Market. If our common stock is removed from listing on The Nasdaq Global Market, it may become more difficult for us to raise funds and may materially limit the trading market of our common stock.

Because stock ownership is concentrated, you and other investors will have minimal influence on stockholders' decisions.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Assuming that outstanding options have not been exercised, Richard B. Hollis, our former Chief Executive Officer and a member of our board of directors, owned approximately 7.9% of our outstanding common stock as of December 31, 2008. Assuming that Mr. Hollis exercised all of his outstanding options that vest within 60 days of December 31, 2008, Mr. Hollis would beneficially own approximately 12.6% of our outstanding common stock. As a result, Mr. Hollis may be able to significantly influence all matters requiring stockholder approval, including the election of directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

Substantial sales of our stock may impact the market price of our common stock.

Future sales of substantial amounts of our common stock, including shares that we may issue upon exercise of options and warrants, could adversely affect the market price of our common stock. Further, if we raise additional funds through the issuance of common stock or securities convertible into or exercisable for common stock, the percentage ownership of our stockholders will be reduced and the price of our common stock may fall.

Issuing preferred stock with rights senior to those of our common stock could adversely affect holders of common stock.

Our charter documents give our board of directors the authority to issue shares of preferred stock without a vote or action by our stockholders. The board also has the authority to determine the terms of preferred stock, including price, preferences and voting rights. The rights granted to holders of preferred stock may adversely affect the rights of holders of our common stock. For example, a series of preferred stock may be granted the right to receive a liquidation preference a pre-set distribution in the event of a liquidation that would reduce the amount available for distribution to holders of common stock. In addition, the issuance of preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock. As a result, common stockholders could be prevented from participating in transactions that would offer an optimal price for their shares.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are currently located at 4435 Eastgate Mall, Suite 400, San Diego, CA 92121, where we have leased approximately 22,000 square feet of office space through December 2009. In addition, we have leased approximately 13,000 square feet of laboratory and office space in San Diego, CA. through November 2009. We believe that our facilities are adequate for our current operations.

Item 3. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. While it is impossible to predict accurately or to determine the eventual outcome of these matters, as of the date of this report, we do not believe that we are engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse effect on our business, financial condition or operating results.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter of 2008.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the Nasdaq Global Market under the symbol HEPH.

The following table sets forth the quarterly high and low sales prices for our common stock from January 1, 2007 through March 27, 2009.

2007		
First Quarter	\$ 6.24	\$ 2.46
Second Quarter	3.10	1.90
Third Quarter	2.64	1.42
Fourth Quarter	2.87	1.48
2008		
First Quarter	\$ 2.09	\$ 1.50
Second Quarter	2.39	1.40
Third Quarter	2.00	0.90
Fourth Quarter	1.37	0.28
2009		
January 1 - March 27	\$ 0.88	\$ 0.32

Performance Measurement Comparison⁽¹⁾

The following graph compares changes through December 31, 2008, in the cumulative total return on our common stock, a broad market index, namely the NASDAQ Composite Index (the NASDAQ Index), and an industry index, namely the NASDAQ Biotechnology Index (the Industry Index). The Industry Index comprises all companies listed on the NASDAQ Stock Market under SIC 283. All values assume reinvestment of the full amount of all dividends as of December 31 of each year.

(1) *The material in this section is not soliciting material, is not deemed filed with the SEC, and is not to be incorporated by reference into any filing of the Company under the 1933 or 1934 Act.*

On March 27, 2008, the closing price of our common stock as reported by the Nasdaq Global Market was \$0.56 share. There were approximately 10,000 shareholders of record and beneficial stockholders of our common stock as of such date. We have not paid cash dividends on our common stock and do not intend to do so in the foreseeable future.

There were no unregistered sales of equity securities in the fourth quarter 2008.

We made no repurchases of our securities during the year ended December 31, 2008.

Item 6. Selected Financial Data

The following data summarizes certain selected financial data for each of the five years ended December 31, 2008 through 2004 and the period from inception (August 15, 1994) to December 31, 2008. The information presented should be read in conjunction with the financial statements and related notes included elsewhere in this report (in thousands, except per share amounts).

	2008	2007	2006	2005	2004	Period from Inception (Aug. 15, 1994) to December 31, 2008
Statement of Operations Data:						
Contract revenues	\$	\$ 645	\$ 444	\$ 56	\$ 63	\$ 1,208
Research and development	16,070(1)	18,319(1)	23,764(1)	18,342	18,488	160,699
General and administrative	6,537(1)	8,150(1)	9,644(1)	9,777	7,216	82,777
Settlement of Dispute				3,000		3,000
Total operating expenses	22,607	26,469	33,408	31,119	25,704	246,476
Interest income (expense)	1,048	2,781	2,741	1,622	917	17,225
Other income (expense)	(6)	(78)	(8)		(33)	(8,163)
Net loss	\$ (21,565)	\$ (23,121)	\$ (30,231)	\$ (29,441)	\$ (24,757)	\$ (236,206)
Net loss per share, basic and diluted	\$ (0.74)	\$ (0.80)	\$ (1.20)	\$ (1.46)	\$ (1.28)	
Weighted average number of common Shares outstanding, basic and diluted	29,060	28,955	25,131	20,125	19,267	
Balance Sheet Data:						
Cash and equivalents	\$ 24,152	\$ 43,215	\$ 67,135	\$ 45,130	\$ 61,991	
Total assets	25,157	45,123	68,512	46,582	63,242	
Total current liabilities.	1,952	3,018	6,734	7,708	5,008	
Stockholders' equity	\$ 23,205	\$ 42,105	\$ 61,778	\$ 38,874	\$ 58,234	

- (1) 2008, 2007 and 2006 Research and development and general and administrative expenses include the expense for stock-based compensation under Statement of Financial Accounting Standards (SFAS) No. 123-R. Stock-based compensation expense was not included in financial results for previous years. (See Accounting for Stock-Based Compensation in the Notes to Financial Statements).

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements elsewhere in this Annual Report on Form 10-K. This discussion and analysis should be read in conjunction with the financial statements and notes included elsewhere in this Annual Report.

General

We are a development-stage pharmaceutical company engaged in the discovery and development of drug candidates for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune or metabolic response due to disease or the process of aging. Our initial technology development efforts are primarily focused on a series of adrenal steroid hormones and hormone analogs that are derived from our Hormonal Signaling Technology Platform.

We have been unprofitable since our inception. As of December 31, 2008, we had an accumulated deficit of approximately \$236.2 million. We expect to incur substantial additional operating losses and capital expenditures for the foreseeable future as we increase expenditures on research and development and begin to allocate significant and increasing resources to clinical testing and other activities in support of the development of our drug candidates. In addition, in the future, we may have to meet the substantial new challenge of developing the capability to market products if we are successful in obtaining regulatory approval for any of our current or future drug candidates. Accordingly, our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and financial information are not indicative of the future operating results or financial condition or ability to operate profitably as a commercial enterprise when and if we succeed in bringing any drug candidates to market.

On March 26, 1997, Hollis-Eden, Inc., a Delaware corporation, was merged with and into us, then known as Initial Acquisition Corp. (IAC), a Delaware corporation. Upon consummation of the merger of Hollis-Eden, Inc. with IAC, Hollis-Eden, Inc. ceased to exist, and IAC changed its name to Hollis-Eden Pharmaceuticals, Inc.

Results of Operations

We have devoted substantially all of our resources to the payment of research and development expenses and general and administrative expenses. From inception through December 31, 2008, we have incurred approximately \$160.7 million in research and development expenses, \$82.8 million in general and administrative expenses, and \$3.0 million in a settlement of dispute. From inception through December 31, 2008 we have generated approximately \$1.2 million in revenues (which resulted from providing research and development services under our Study Funding Agreement with CFFT). We have earned \$9.1 million in other income. The other income and expense is comprised of \$7.6 million in deemed discount expense, \$0.4 million in interest expense and a \$0.1 million loss on disposal of assets. These expenses have been offset by \$17.2 million in interest income. The combination of these resulted in a net loss of \$236.2 million for the period from inception until December 31, 2008.

Research and development and general and administrative expenses include the expense for stock-based compensation for the years ended December 31, 2008, 2007 and 2006, (See Accounting for Stock-Based Compensation in the Notes to Financial Statements).

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Research and development expenses were \$16.1 million, \$18.3 million and \$23.8 million in 2008, 2007 and 2006, respectively. The research and development expenses relate primarily to the ongoing development, preclinical testing and clinical trials for our drug candidates. Research and development expenses decreased \$2.2 million in 2008 compared to 2007, due primarily to a decrease in headcount, bonuses, and a decline in preclinical development offset by an increase in clinical trial expenses. The decrease of \$5.5 million in research and development expenses in 2007 compared to 2006, was due mainly to the discontinuation of our NEUMUNE (HE2100) research and development program.

General and administrative expenses were \$6.5 million, \$8.1 million and \$9.6 million in 2008, 2007 and 2006, respectively. General and administrative expenses relate to salaries and benefits, facilities, patent fees, legal, accounting/auditing, investor relations, consultants, insurance and travel. General and administrative expenses decreased \$1.6 million in 2008 compared to 2007 due primarily to a decrease in executive head count, bonuses, Directors and Officers insurance, and in accounting and consulting fees. General and administrative expenses decreased \$1.5 million in 2007 compared to 2006, due primarily to a decrease in executive head count mid year and in legal costs and consulting fees.

Other income and expenses were \$1.0 million, \$2.7 million and \$2.7 million in 2008, 2007 and 2006, respectively. The \$1.7 million decrease in other income and expense for 2008 compared to 2007 was due mainly to lower interest rates and lower cash balances. During 2007 and 2006, we earned interest income totaling \$2.7 million and \$2.7 million, respectively. The interest income increase in 2007 compared to 2006 was due to higher interest rates.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of shares of common stock. During the year ended December 31, 1995, we received cash proceeds of \$250,000 from the sale of securities. In May 1996, we completed a private placement of shares of common stock, from which we received aggregate gross proceeds of \$1.3 million. In March 1997, the Merger of IAC and Hollis-Eden, Inc. provided us with \$6.5 million in cash and other receivables. In May 1998, we completed a private placement of common stock and warrants, from which we received gross proceeds of \$20 million. During January 1999, we completed two private placements of common stock raising approximately \$25 million. In December 2001, we completed a private placement of common stock and warrants, from which we received gross proceeds of \$11.5 million. In February 2003, we completed a private placement of convertible debentures and warrants, from which we received gross proceeds of \$10.0 million. In June 2003, we completed a private placement of common stock and warrants, from which we received gross proceeds of \$14.7 million. In October 2003 we completed a public offering of our common stock from which we received \$62.5 million in gross proceeds. In June 2005, we completed a sale of shares of our common stock and warrants from which we received \$10.0 million in gross proceeds. During 2006 (in February and in November), we completed two sales of shares of our common stock and warrants from which we received, in the aggregate gross proceeds of approximately \$52.0 million. In addition, we have received a total of \$17.8 million from the exercise of warrants and stock options from inception.

On June 20, 2003, convertible debentures with a face value of \$0.5 million were converted into 87,720 shares of our common stock, leaving a \$9.5 million aggregate principal amount of convertible debentures outstanding.

We became entitled to convert the outstanding debentures into common stock in August 2003 and the remaining aggregate principal amount of convertible debentures with a face value of \$9.5 million were converted into 1,666,680 shares of our common stock with a value of \$5.70 per share.

A summary of our current contractual obligations is as follows (in thousands):

Contractual Obligations	Total	Payments Due by Period			
		Less than one year	One to three years	Three to five years	More than Five years
Operating Leases	\$ 1,170	\$ 1,157	\$ 13	\$	\$

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

We may also be required to make substantial milestone or royalty payments in cash based on the terms of some of our agreements (See Note 6 to the Financial Statements).

Our operations to date have consumed substantial capital without generating any revenues other than the amount received under our collaboration with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT). We will

continue to require substantial and increasing amounts of funds to conduct necessary research and development and preclinical and clinical testing of our drug candidates, and to market any drug candidates that receive regulatory approval. We do not expect to generate revenue from operations for the foreseeable future, and our ability to meet our cash obligations as they become due and payable may depend for at least the next several years on our ability to sell securities, borrow funds or some combination thereof. Based upon our current plans, we believe that our existing capital resources, together with interest thereon, will be sufficient to meet our operating expenses and capital requirements for at least the next 12 months. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may not be successful in raising necessary funds. As of December 31, 2008, our cash and cash equivalents totaled approximately \$24.2 million.

Our future capital requirements will depend upon many factors, including progress with preclinical testing and clinical trials, the number and breadth of our programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, and our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We may incur increasing negative cash flows and net losses for the foreseeable future. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

Critical Accounting Policies

Certain of our accounting policies require the application of judgment and estimates by management, which may be affected by different assumptions and conditions. These estimates are typically based on historical experience, terms of existing contracts, trends in the industry and information available from other outside sources, as appropriate. We believe the estimates and judgments associated with our reported amounts are appropriate in the circumstances. Actual results could materially vary from those estimates under different assumptions or conditions.

All research and development costs are expensed as incurred. The value of acquired in-process research and development is charged to expense on the date of acquisition. Research and development expenses include, but are not limited to, acquired in-process technology deemed to have no alternative future use, license fees related to license agreements, preclinical and clinical trial studies, payroll and personnel expense, and lab supplies, consulting and research-related overhead. Research and development expenses paid in the form of cash and our stock to related parties aggregated \$11.5 million for the period from inception (August 15, 1994) to December 31, 2003 (see Note 6, Colthurst, Edenland and Mr. Prendergest and Aeson Therapeutics). No such related party expenses were incurred in 2008, 2007 or 2006.

In December 2006, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. EITF 00-19-2, *Accounting for Registration Payment Arrangements* (FSP EITF 00-19-2). FSP EITF 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5,

Accounting for Contingencies. The guidance in FSP EITF 00-19-2 amends FASB Statement No. 133, *Accounting for Derivative Financial Instruments and Hedging Activities*, and No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and FASB's Interpretation No. (FIN) 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* to include scope exceptions for registration payment arrangements. This FSP is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this guidance shall be effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We have adopted EITF 00-19-2 as of December 31, 2006 and it did not have a material impact on our financial statements.

In September 2007, the EITF reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities*. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. This Issue is effective for fiscal years beginning after December 15, 2007, and earlier application is not permitted. The pronouncement has had no material effect on the Company's financial statements.

As of January 1, 2006, we account for stock-based compensation in accordance with SFAS 123-R, *Share based payments*. Under the fair value recognition provisions of this statement, share-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-based awards at the grant date requires judgment, including estimating our stock price volatility and employee stock option exercise behavior. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Our expected volatility is based upon the historical volatility of our stock. We have chosen to utilize the safe harbor expected life for our options. Because stock-based compensation expense is recognized in our statement of operations based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. SFAS 123-R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. If factors change and we employ different assumptions in the application of SFAS 123-R, the compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

On July 13, 2006, FIN 48, *Accounting for Uncertainty in Income Taxes*, which is effective for fiscal years beginning after December 15, 2006, which establishes recognition and measurement thresholds that must be met before a tax benefit can be recognized in the financial statements. The Company has adopted FIN 48 on January 1, 2007, and it has had no material impact on its financial statements.

Impact of Recently Issued Accounting Pronouncements

At its December 2007 meeting, FASB, ratified the consensus reached by the Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1). EITF 07-1 concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity's business and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company does not believe the adoption of this standard will have a material impact on its financial statements.

In December 2007, the FASB issued SFAS, No. 141(R), *Business Combinations*, (SFAS 141(R)), which replaces SFAS No. 141, *Business Combinations* and requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their

fair values as of that date, with limited exceptions. SFAS 141(R) also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. SFAS 141(R) makes various other amendments to authoritative literature intended to provide additional guidance or to confirm the guidance in that literature to that provided in this Statement. SFAS 141(R) applies to business combinations for which the acquisition date is in fiscal years beginning after December 15, 2008. The Company does not believe the adoption of this standard will have a material impact on its financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 sets forth the level of authority to a given accounting pronouncement or document by category. Where there might be conflicting guidance between two categories, the more authoritative category will prevail. SFAS 162 became effective on November 15, 2008. SFAS 162 has no effect on the Company's financial position, statement of operations, or cash flows at this time.

We adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157) effective January 1, 2008 which had no material impact on the Company's financial statements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. SFAS 157 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;

Level 2, defined as inputs other than quoted prices in active markets that are directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant value drivers are observable.

Our level 1 assets primarily include our cash and cash equivalents (mainly money market accounts) and due to the immediate or short-term maturities of these financial instruments. Valuations are obtained from readily available pricing sources. We do not currently have Level 2 or 3 assets. We do not have any debt instruments as of December 31, 2008 and 2007

In February 2008, Financial Accounting Standards Board (FASB) Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2) was issued. FSP 157-2 delays the adoption of SFAS 157 for nonfinancial assets and liabilities until fiscal years beginning after November 15, 2008. The Company is currently in the process of evaluating whether the adoption of FSP 157-2 will have a material impact on its financial statements.

On October 10, 2008, the FASB issued FASB Staff Position No. FAS 157-3, *Determining the Fair Value of a Financial Asset in a Market That Is Not Active* (FSP 157-3), which clarifies the application of SFAS 157 in an inactive market and provides an illustrative example to demonstrate how the fair value of a financial asset is determined when the market for that financial asset is inactive. FSP 157-3 was issued on October 10, 2008 and is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of FSP 157-3 had no impact on the Company's financial statements.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 allows eligible financial assets and liabilities to be measured at fair value that are not otherwise measured at fair value. If the fair

value option for an eligible item is elected, unrealized gains and losses for that item are reported in earnings at each reporting date. SFAS 159 also establishes presentation and disclosure requirements designed to draw comparisons between the different measurement attributes the Company elects for similar types of assets and liabilities. The Company has adopted the pronouncement and it has had no material effect on its financial statements.

Off-Balance Sheet Arrangements

Hollis Eden Pharmaceuticals, Inc. currently does not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

At December 31, 2008, our investment portfolio included only cash and money market accounts and did not contain fixed-income securities, with the exception of a small amount held in a restricted CD. There would be no material impact to our investment portfolio, in the short term, associated with any change in interest rates, and any decline in interest rates over time will reduce our interest income, while increases in interest rates over time will increase our interest income.

Item 8. Financial Statements and Supplementary Data

	Page
<u>Balance Sheets as of December 31, 2008 and 2007</u>	34
<u>Statements of Operations for the Fiscal Years Ended December 31, 2008, December 31, 2007, December 31, 2006 and the Period From Inception (August 15, 1994) to December 31, 2008</u>	35
<u>Statements of Stockholders' Equity for the Fiscal Years Ended December 31, 1994, December 31, 1995, December 31, 1996, December 31, 1997, December 31, 1998, December 31, 1999, December 31, 2000, December 31, 2001, December 31, 2002, December 31, 2003, December 31, 2004, December 31, 2005, December 31, 2006, December 31, 2007 and December 31, 2008</u>	36
<u>Statements of Cash Flow for the Fiscal Years Ended December 31, 2008, December 31, 2007, December 31, 2006 and the Period from Inception (August 15, 1994) to December 31, 2008</u>	41
<u>Notes to Financial Statements</u>	42
<u>Report of Independent Registered Public Accounting Firm</u>	69

Hollis-Eden Pharmaceuticals, Inc.**(A Development Stage Company)****Balance Sheets**

	December 31,	
	2008	2007
	(In thousands, except par value)	
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 24,152	\$ 43,215
Prepaid expenses	262	269
Deposits	7	7
Other receivables		645
Total current assets	24,421	44,136
Property and equipment, net of accumulated depreciation of \$1,496 and \$1,213	641	892
Deposits	61	61
Restricted cash	34	34
Total assets	\$ 25,157	\$ 45,123
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable	\$ 323	\$ 455
Accrued expenses	1,629	2,563
Total current liabilities	1,952	3,018
Commitments and contingencies (Notes 6, 11, 12)		
Stockholders' equity: (Notes 3, 7, 8, 9, 10)		
Preferred stock, \$.01, 10,000 shares authorized; no shares issued or outstanding		
Common stock, \$.01 par value, 50,000 shares authorized; 29,228 and 29,064 shares issued and 29,169 and 29,005 outstanding respectively	292	291
Capital in excess of par value	259,465	256,801
Cost of repurchased common stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(236,206)	(214,641)
Total stockholders' equity	23,205	42,105
Total liabilities and stockholders' equity	\$ 25,157	\$ 45,123

The accompanying notes are an integral part of these financial statements.

Hollis-Eden Pharmaceuticals, Inc.**(A Development Stage Company)****Statements of Operations**

	For the years ended December 31,			Period from
	2008	2007	2006	Inception (Aug.15, 1994) to December 31, 2008
	(In thousands, except per share amounts)			
Revenue:				
Contract R&D revenue	\$	\$ 645	\$ 444	\$ 1,208
Total revenue		645	444	1,208
Operating expenses:				
Research and development				
R & D operating expenses	15,092	17,074	22,177	151,222
R & D costs related to common stock and stock option grants for collaborations and technology purchases	978	1,245	1,587	9,477
Total research and development	16,070	18,319	23,764	160,699
General and administrative				
G & A operating expenses	5,025	6,160	7,365	64,624
G & A costs related to options / warrants granted	1,512	1,990	2,279	18,153
Total general and administrative	6,537	8,150	9,644	82,777
Settlement of dispute				3,000
Total operating expenses	22,607	26,469	33,408	246,476
Other income (expense):				
Loss on disposition of assets	(6)	(78)	(8)	(148)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures				(7,627)
Interest income	1,048	2,781	2,741	17,225
Interest expense				(388)
Total other income, net	1,042	2,703	2,733	9,062
Net loss	\$ (21,565)	\$ (23,121)	\$ (30,231)	\$ (236,206)
Net loss per share, basic and diluted	\$ (0.74)	\$ (0.80)	\$ (1.20)	
Weighted average number of common shares outstanding, basic and diluted	29,060	28,955	25,131	

The accompanying notes are an integral part of these financial statements.

Hollis-Eden Pharmaceuticals, Inc.**(A Development Stage Company)****Statements of Stockholders Equity**

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Contribution by stockholder		\$		\$	\$ 103			\$	\$ 103
Common stock issued for cash			2,853		25				25
Common stock issued as consideration for the license agreements (Note 6)			543		5				5
Net loss								(1,277)	(1,277)
Balance at December 31, 1994			3,396		133			(1,277)	(1,144)
Common stock issued for cash			679		250				250
Common stock issued as consideration for amendments to the license agreements (Note 6)			76		28				28
Net loss								(672)	(672)
Balance at December 31, 1995			4,151		411			(1,949)	(1,538)
Common stock issued in conversion of debt (Note 7)			165		371				371
Common stock issued for cash, net of expenses (Note 7)			580		1,234				1,234
Common stock issued as consideration for termination of a finance agreement			15		34				34
Warrants issued to consultants for services rendered					24				24
Net loss								(692)	(692)
Balance at December 31, 1996			4,911		2,074			(2,641)	(567)
Recapitalization of Company upon the merger with Initial Acquisition Corp. (Note 3)			883	58	6,213				6,271
Warrants issued to a certain director upon the successful closure of the merger (Note 3)					570				570
Exercise of warrants, net of expenses			978	10	5,619				5,629
Amortization of deferred compensation					282				282
Exercise of stock options					1				1
Net loss								(5,253)	(5,253)
Balance at December 31, 1997			6,772	68	14,759			(7,894)	6,933
Exercise of warrants			399	4	1,196				1,200
Exercise of stock options			53	1	155				156

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Stockholders Equity (Continued)

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Private Placement, net of expenses (Note 7)	4		1,329	13	19,877				19,890
Warrants issued for services in lieu of cash (Note 10)					408				408
Stock issued for license fee (Note 6)			33		500				500
Stock issued for services in lieu of cash			6		95				95
Options issued for services in lieu of cash (Note 9)					240				240
Amortization of deferred compensation					308				308
Net loss								(5,427)	(5,427)
Balance at December 31, 1998	4		8,592	86	37,538			(13,321)	24,303
Exercise of warrants			755	8	5,136				5,144
Exercise of stock options			10		75				75
Private Placement, net of expenses (Note 7)			1,368	14	24,759				24,773
Preferred Stock Conversion (Note 7,8)	(4)		346	3	(3)				
Deferred compensation-Options forfeited (Note 9)					51				51
Amortization of non-employee options					559				559
Warrants issued for services in lieu of cash (Note 10)					2,140				2,140
Options accelerated vesting (Note 9)					4,900				4,900
Net loss								(15,320)	(15,320)
Balance at December 31, 1999			11,071	111	75,155			(28,641)	46,625
Exercise of warrants			133	2	758				760
Exercise of stock options			1		5				5
Common Stock issued for 401(k)/401(m) plan			6		63				63
Common Stock issued for In-Process R&D (Note 6)			209	2	1,998				2,000
Options granted for license fee			38		598				598
Amortization of non-employee options					79				79
Common Stock issued for purchase of technology			132	1	1,847				1,848
Net loss								(19,515)	(19,515)
Balance at December 31, 2000			11,590	116	80,503			(48,156)	32,463

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Stockholders Equity (Continued)

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Exercise of stock options			10		22				22
Common Stock issued for 401(k)/401(m) plan			16		96				96
Private Placement, net of expenses (Note 7)			1,280	13	10,644				10,657
Warrants issued for services in lieu of cash (Note 10)					80				80
Amortization of non-employee options					96				96
Warrants issued for services					208				208
Net loss								(15,762)	(15,762)
Balance at December 31, 2001			12,896	129	91,649			(63,918)	27,860
Exercise of stock options					2				2
Common Stock issued for 401(k)/401(m) plan			26		137				137
Common Stock issued for sublicense agreement (Note 6)			50	1	204				205
Common Stock issued to consultants					17				17
Amortization of non-employee options					66				66
Warrants issued for services					247				247
Net loss								(17,502)	(17,502)
Balance at December 31, 2002			12,972	130	92,322			(81,420)	11,032
Common Stock issued for 401(k)/401(m) plan			32		223				223
Exercise of warrants			467	5	3,323				3,328
Exercise of stock options			85	1	955				956
Stock options issued					561				561
Private Placement, net of expenses			1,283	13	14,290				14,303
Common Stock issued for sublicense agreement (Note 6)			119	1	644				645
Common Stock issued for milestone payment			50	1	281				282
Debt Conversion			1,755	17	9,983				10,000
Common Stock issued in lieu of cash / interest			9		142				142
Public Offering, net of expenses			2,500	25	58,576				58,601
Deemed discount on convertible debentures					6,470				6,470
Warrants issued for services					1,398				1,398
Amortization of non-employee options					128				128
Purchase of treasury stock						(59)	(346)		(346)

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Net loss						(25,671)	(25,671)
Balance at December 31, 2003	19,272	193	189,296	(59)	(346)	(107,091)	82,052

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Stockholders Equity (Continued)

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Common Stock issued for 401(k) plan			17		147				147
Exercise of warrants			6		11				11
Exercise of stock options			4		16				16
Common Stock issued for In-Process R&D (Note 6)			48		629				629
Amortization of non-employee options					136				136
Net loss							(24,757)		(24,757)
Balance at December 31, 2004			19,347	193	190,235	(59)	(346)	(131,848)	58,234
Common Stock issued for 401(k) plan			25		151				151
Exercise of warrants			42	1	260				261
Exercise of stock options			35	1	123				124
Public Offering, net of expenses (Note 7)			1,333	13	9,502				9,515
Amortization of non-employee options					30				30
Net loss							(29,441)		(29,441)
Balance at December 31, 2005			20,782	208	200,301	(59)	(346)	(161,289)	38,874
Common Stock issued for 401(k) plan			45	1	224				225
Exercise of warrants			10		1				1
Warrants issued to consultants					226				226
Exercise of stock options			34		86				86
Private Placements, net of expenses			8,000	80	48,697				48,777
Amortization of FAS 123R employee options					3,534				3,534
Amortization of non-employee warrants					13				13
Restricted stock grant, net of forfeitures			65	1	401				402
Common Stock issued for In-Process R&D			35		180				180
Deferred Compensation					(309)				(309)
Net loss							(30,231)		(30,231)
Balance at December 31, 2006			28,971	290	253,354	(59)	(346)	(191,520)	61,778
Common Stock issued for 401(k) plan			96	1	192				193
Exercise of stock options			9		20				20

Hollis-Eden Pharmaceuticals, Inc.**(A Development Stage Company)****Statements of Stockholders Equity (Continued)**

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Amortization of FAS 123R employee options					3,128				3,128
Restricted Stock Forfeitures			(12)		(33)				(33)
Amortization of non-employee warrants					17				17
Deferred Compensation					123				123
Net loss								(23,121)	(23,121)
Balance at December 31, 2007			29,064	291	256,801	(59)	(346)	(214,641)	42,105
Common Stock issued for 401(k) plan			164	1	174				175
Amortization of FAS 123R employee options					2,404				2,404
Deferred Compensation					86				86
Net loss								(21,565)	(21,565)
Balance at December 31, 2008			29,228	\$ 292	\$ 259,465	(59)	\$ (346)	\$ (236,206)	\$ 23,205

The accompanying notes are an integral part of these financial statements.

Hollis-Eden Pharmaceuticals, Inc.**(A Development Stage Company)****Statements of Cash Flows**

	For the Years Ended			Period from
	2008	2007	2006	Inception (Aug. 15, 1994) to December 31, 2008
	(In thousands)			
Cash flows from operating activities:				
Net loss	\$ (21,565)	\$ (23,121)	\$ (30,231)	\$ (236,206)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	315	309	294	2,014
Disposal of assets	6	85	8	162
Compensation expense related to equity awards	2,404	3,128	3,534	9,066
Compensation expense related to restricted stock	86	90	93	269
Amortization of deemed discount on convertible debentures				6,470
Amortization of deferred issuance cost				1,157
Common stock issued for 401k/401m plan	175	192	225	1,410
Common stock issued as consideration for amendments to the license agreements				33
Common stock issued as consideration for termination of a finance agreement				34
Common stock and options issued as consideration for license fees, milestone payment, interest and services				2,859
Expense related to warrants issued as consideration to consultants		17	239	4,369
Expense related to warrants issued to a director for successful closure of merger				570
Expense related to stock options issued				5,718
Expense related to common stock issued for the purchase of technology				1,848
Common stock issued as consideration for In-Process R&D			180	2,809
Deferred compensation expense related to options issued				1,210
Changes in assets and liabilities:				
Prepaid expenses	7	(81)	16	(262)
Deposits		32	14	(68)
Other receivables	645	(645)	8	
Other Receivable from related party		4	7	
Accounts payable	(132)	(170)	341	1,014
Accrued expenses	(934)	(3,546)	(1,315)	1,582
Net cash used in operating activities	(18,993)	(23,706)	(26,587)	(193,942)
Cash flows provided by investing activities:				
Purchase of property and equipment	(70)	(234)	(237)	(2,816)
Net cash used in investing activities	(70)	(234)	(237)	(2,816)
Cash flows from financing activities:				
Restricted Cash			(34)	(34)
Contributions from stockholder				104
Net proceeds from sale of preferred stock				4,000
Net proceeds from sale of common stock			48,777	183,534
Net proceeds from issuance of convertible debentures and warrants				9,214
Purchase of treasury stock				(346)
Proceeds from issuance of debt				371
Net proceeds from recapitalization				6,271
Net proceeds from warrants/options exercised		20	86	17,796

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Net cash provided by financing activities		20	48,829	220,910
Net increase (decrease) in cash and equivalents	(19,063)	(23,920)	22,005	24,152
Cash and equivalents at beginning of period	43,215	67,135	45,130	
Cash and equivalents at end of period	\$ 24,152	\$ 43,215	\$ 67,135	\$ 24,152
Supplemental disclosure of cash flow information:				
Interest paid	\$	\$	\$	\$ 388
Conversion of debt to equity				10,371
Warrants issued to consultants in lieu of cash, no vesting				559
Warrants issued in lieu of cash, commissions on private placement				733
Warrants issued in connection with convertible debentures				371

The accompanying notes are an integral part of these financial statements.

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements****1. The Company**

Hollis-Eden Pharmaceuticals, Inc. (Hollis-Eden or the Company), a development stage pharmaceutical company, is engaged in the discovery and development of products for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune response. From inception (August 15, 1994) through March 1997, the Company's efforts were directed toward organizing, licensing technology and preparing for offerings of shares of its common stock. Since 1997, the Company has been expanding its intellectual property, developing its lead drug candidates, performing preclinical tests and has entered into multiple clinical studies. The Company's technology development efforts are focused on a series of potent hormones and hormone analogs that the Company believes are key components of the body's natural regulatory system. Beginning in the second quarter of 2004, the Company has been generating a small amount of revenue. This revenue resulted from providing research and development services under the Company's Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc. To date, the Company has not developed commercial products or generated any product sales for the period since inception (August 15, 1994 through December 31, 2008).

2. Summary of Accounting Policies*Cash Equivalents*

The Company considers any liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2008 the Company's cash equivalents are approximately \$24.2 million and are deposited primarily in a money market account with a large financial institution.

Property and Equipment

Property and equipment are stated at cost. The Company provides for depreciation using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the lease term or the useful life. The cost of major additions and improvements is capitalized, while maintenance and repair costs that do not improve or extend the lives of the respective assets are charged to operations as incurred.

Property and equipment balances and corresponding lives were as follows:

	December 31		
	2008	2007	Lives
	(in thousands)		
Leasehold improvements	\$ 23	\$ 23	3 years

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Machinery, equipment and information systems	1,896	1,864	5-7 years
Furniture and fixtures	218	218	5-7 years
Total	2,137	2,105	
Less: Accumulated depreciation and amortization	(1,496)	(1,213)	
	\$ 641	\$ 892	

Depreciation expense associated with property and equipment was approximately \$315,000, \$309,000 and \$294,000 in 2008, 2007 and 2006, respectively.

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), the Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which there is identifiable assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. The Company had no impairments in 2008, 2007 and 2006.

Accrued Expenses

Accrued expenses include approximately \$0.5 million and \$0.5 million in accrued vacation expense, \$0.0 million and \$0.7 million in accrued salary/ bonus expense and \$1.1 million and \$1.3 million in other research and development / general and administrative expenses as of December 31, 2008 and 2007, respectively.

Revenue Recognition

In December 2003, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 104 *Revenue Recognition* (SAB 104), which updates and summarizes the Commission's views on the application of generally accepted accounting principles to revenue recognition in financial statements. The Company believes that its revenue recognition policies conform to the requirements of SAB 104.

Contract revenue is recognized as the services are performed on a cost reimbursement basis. Revenue associated with development milestones, if any, is recognized based upon the achievement of the milestones, as defined in the respective agreements. Overall, revenue is considered to be realized or realizable and earned when there is persuasive evidence of a revenue arrangement in the form of a contract or purchase order, the services have been performed, the price is fixed or determinable and collectability is reasonably assured.

Research and Development

All research and development costs are expensed as incurred. The value of acquired in-process research and development is charged to expense on the date of acquisition. Research and development expenses include, but are not limited to, acquired in-process technology deemed to have no alternative future use, license fees related to license agreements, preclinical and clinical trial studies, payroll and personnel expense, lab supplies, consulting and research-related overhead. Research and development expenses paid in the form of cash and Company stock to related parties aggregated \$11.5 million for the period from inception (August 15, 1994) to December 31, 2003 (see Note 6, Colthurst, Edenland and Mr. Prendergest and Aeson Therapeutics). No such related party expenses were incurred in 2008, 2007 or 2006.

Accounting for Stock-Based Compensation

The Company has an equity-based incentive compensation plan known as The 2005 Equity Incentive Plan (the Plan). The Plan allows us to grant stock options and other stock or stock-based awards, including stock appreciation rights, stock purchase awards, restricted stock awards and restricted stock units awards. The Plan also allows us to provide equity compensation to non-employee directors and consultants. The exercise price for an option granted under the Plan is typically not less than the fair market value of the common stock subject to such option. The term of any options granted under the Plan may not exceed 10 years from the date of the grant. Options issued to employees generally vest over a four-year period, with 25% vesting on the first anniversary date and the balance vesting monthly during years two, three and four.

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)**

Prior to January 1, 2006, we applied Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (*APB25*), and related interpretations in accounting for options. All stock options for employees (with the exception of three grants) have been granted at or above the market price where the exercise price of the option equaled or exceeded the market price of the stock on the date of the grant. As a result, under APB 25 there was no stock-based compensation expense for those grants. Compensation expense was taken for the three options granted at below market value (see 2005 Annual Report on Form 10-K, Notes to Financial Statements *No. 9 Stock Options* for more detail). As of December 31, 2008 the Plan has 8,229,139 shares of common stock reserved for issuance.

Effective January 1, 2006, we adopted SFAS No. 123 (Revised 2004), *Share-Based Payment* (SFAS 123R), requiring us to recognize expense related to the fair value of our stock-based compensation awards. We elected the modified prospective transition method as permitted by SFAS 123R; accordingly, results from prior periods have not been restated. Under this transition method, stock-based compensation expense for the fiscal year ended December 31, 2008, 2007 and 2006 includes:

- a) compensation expense for all stock-based compensation awards granted prior to January 1, 2006 but not yet vested, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, *Accounting for Stock-Based Compensation*, and
- b) compensation expense for all stock-based compensation awards granted subsequent to December 31, 2005 based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect the Company's experience. Compensation expense is recognized using the straight-line method for all stock-based awards issued after January 1, 2006. Compensation expense is recognized only for those options expected to vest, with forfeitures estimated at the date of grant based on the Company's historical experience and future expectations. Prior to the adoption of SFAS 123R, the effect of forfeitures on the pro forma expense amounts was not recognized. SFAS 123R requires forfeitures to be estimated at the time of the grant and revised as necessary in subsequent periods if actual forfeitures differ from those estimates.

Black-Scholes Option Valuation Assumptions(1)

	Fiscal Years Ended		
	December 31, 2008	December 31, 2007	December 31, 2006
Risk-free interest rate	3.75%	4.75%	4.75%
Expected dividend yield	0%	0%	0%
Expected life(2)	6.60 years	6.25 years	6.25 years
Expected volatility(3)	75%	76%	84%

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

- (1) Forfeitures are estimated as 6.20% for 2008, 5.05% for 2007 and 2% for 2006 based on historical experience.
- (2) The 2008 expected life is based on historical experience, the 2007 and 2006 expected life is based on the safe-harbor method as described in SEC SAB No. 107.
- (3) The expected stock price volatility is estimated based on historical experience.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company s

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

employee stock options have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of the Company's options.

In November 2005, the FASB issued SFAS 123R-3, *Transition Election to Accounting for the Tax Effects of Share-Based Payment Awards*. This requires an entity to follow either the transition guidance (long method) for the additional-paid-in-capital pool, or the alternative transition (simplified method) as described in the pronouncement. We have decided to use the alternative transition (simplified method) for accounting for the tax effects of our share-based payment awards.

401(k) Matching Contributions

Our Company sponsors a 401(k) savings plan, to which eligible domestic employees may voluntarily contribute a portion of their income, subject to statutory limitations. In addition to the participant's own contributions to these 401(k) savings plans, we match such contributions up to a designated level. Total matching contributions related to employee savings plans were approximately \$175,000, \$192,000 and \$199,000 in 2008, 2007 and 2006, respectively.

Income Taxes

The Company provides for income taxes under the principles of SFAS 109 which requires that provision be made for taxes currently due and for the expected future tax effects of temporary differences between book and tax bases of assets and liabilities.

On July 13, 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), which establishes recognition and measurement thresholds that must be met before a tax benefit can be recognized in the financial statements. The Company adopted FIN 48 on January 1, 2007. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN No. 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Based on the evaluation, the Company has concluded that there are no significant uncertain tax positions requiring recognition in the financial statements. If the Company is required to recognize any interest and penalties accrued related to unrecognized tax benefits, such amounts will be recognized as tax expense. To date, the Company has not recognized such interest or penalties.

Financial Instruments

The Company's financial instruments consist primarily of cash and accounts payable. These financial instruments are stated at their respective carrying values, which approximate their fair values, due to their short-term nature.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could materially differ from those estimates.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

Concentrations of Risk

Financial instruments, which potentially expose the Company to concentrations of credit risk, consist primarily of cash and cash equivalents. The Company places its cash with high quality financial institutions. Cash balances are generally substantially in excess of the amounts insured by the Federal Deposit Insurance Corporation.

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed in a manner consistent with basic net loss per share after giving effect to potentially dilutive securities. Potential common shares of 9,466,150, 9,702,428 and 9,939,430 related to the Company's outstanding stock option and warrants were excluded from the computation of diluted net loss per share for the years ended December 31, 2008, 2007 and 2006 because their effect on net loss per share is anti-dilutive.

Recent Accounting Pronouncements

At its December 2007 meeting, FASB, ratified the consensus reached by the Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1). EITF 07-1 concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity's business and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company does not believe the adoption of this standard will have a material impact on its financial statements.

In December 2007, the FASB issued SFAS, No. 141(R), *Business Combinations*, (SFAS 141(R)), which replaces SFAS No. 141, *Business Combinations* and requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. SFAS 141(R) also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. SFAS 141(R) makes various other amendments to authoritative literature intended to provide additional guidance or to confirm the guidance in that literature to that provided in this Statement. SFAS 141(R) applies to business combinations for

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

which the acquisition date is in fiscal years beginning after December 15, 2008. The Company does not believe the adoption of this standard will have a material impact on its financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (*SFAS 162*). SFAS 162 sets forth the level of authority to a given accounting pronouncement or document by category. Where there might be conflicting guidance between two categories, the more authoritative category will prevail. SFAS 162 became effective on November 15, 2008. SFAS 162 has no effect on the Company's financial position, statement of operations, or cash flows at this time.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes criteria to be considered when measuring fair value and expands disclosures about fair value measurements. In February 2008, Financial Accounting Standards Board (FASB) Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2) was issued. FSP 157-2 delays the adoption of SFAS 157 for nonfinancial assets and liabilities until fiscal years beginning after November 15, 2008. SFAS 157 does not modify any currently existing accounting pronouncements. The Company adopted SFAS 157 effective January 1, 2008 and it did not have a material impact on the Company's financial statements (see Note 13). The Company is currently in the process of evaluating whether the adoption of FSP 157-2 will have a material impact on its financial statements.

On October 10, 2008, the FASB issued FASB Staff Position No. FAS 157-3, *Determining the Fair Value of a Financial Asset in a Market That Is Not Active* (FSP 157-3), which clarifies the application of SFAS 157 in an inactive market and provides an illustrative example to demonstrate how the fair value of a financial asset is determined when the market for that financial asset is inactive. FSP 157-3 was issued on October 10, 2008 and is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of FSP 157-3 had no impact on the Company's financial statements.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 allows eligible financial assets and liabilities to be measured at fair value that are not otherwise measured at fair value. If the fair value option for an eligible item is elected, unrealized gains and losses for that item are reported in earnings at each reporting date. SFAS 159 also establishes presentation and disclosure requirements designed to draw comparisons between the different measurement attributes the Company elects for similar types of assets and liabilities. The Company has adopted the pronouncement and it has had no material effect on its financial statements.

3. Recapitalization

During March 1997, Hollis-Eden Inc. was merged (the Merger) with and into the Company (then known as Initial Acquisition Corp. (IAC)). Upon consummation of the Merger, Hollis-Eden Inc. ceased to exist, and IAC changed its name to Hollis-Eden Pharmaceuticals, Inc. IAC (now called Hollis-Eden Pharmaceuticals, Inc.) remains the continuing legal entity and registrant for SEC reporting purposes. The Merger was accounted for as a recapitalization of Hollis-Eden Inc. by an exchange of Common Stock of Hollis-Eden Inc., for the net assets of IAC, consisting primarily of \$6.5 million in cash and other receivables.

Under the terms of the merger agreement, each share of Hollis-Eden Inc. Common Stock outstanding converted into one share of Common Stock of Hollis-Eden Pharmaceuticals, Inc. Common Stock (Company Common Stock), and all warrants and options to purchase Hollis-Eden Inc. Common Stock outstanding converted into the right to receive the same number of shares of Company Common Stock.

Upon the consummation of the Merger, pursuant to an agreement, the Company issued warrants to purchase an aggregate of 50,000 shares of Company Common Stock at an exercise price of \$0.10 per share to a director and former officer. Additional paid-in capital was increased by \$570,000 with an offsetting \$570,000 charge recorded to operations during the three months ended March 31, 1997.

4. Other Receivable from Related Party

On April 23, 2001, the Company entered into a promissory note with a stockholder/officer in the amount of \$16,875. Interest was at 4.5% per annum. The promissory note was paid in full prior to the due date of April 23, 2004.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

On May 22, 1998, the Company entered into a promissory note with a stockholder/officer in the amount of \$200,000. Interest was at 5.5% per annum. The note was repaid in full in May 2003.

On March 21, 2005, the Company entered into a promissory note with an employee with a maximum loan amount of \$20,000. Interest was at 6% per annum. The first installment of \$10,000 was made on the commencement date. A second installment of \$10,000 was made on April 20, 2005. The loan was repaid with a balance of approximately \$2,000 forgiven on May 10, 2007.

5. Income Taxes

The Company has available a Federal and state net operating loss carryforward of approximately \$193.4 million, \$175.4 million and \$156.7 million and \$149.5 million, \$131.1 million and \$112.3 million at December 31, 2008, 2007 and 2006, respectively, which may be carried forward as an offset to taxable income, if any, in future years through its expiration for California in 2018 and for Federal in 2028. The Company has a net Federal and state deferred tax asset of approximately \$75.6 million, \$68.3 million and \$61.0 million and \$16.4 million, \$14.3 million and \$12.3 million, at December 31, 2008, 2007 and 2006, respectively, comprised of research and development credits and the net operating loss carryforward. The net deferred tax assets have been fully reserved due to the uncertainty of the Company being able to generate taxable income under the more likely than not criteria of SFAS 109. The Federal and state net operating loss carryforwards begin expiring in 2017 and 2010, respectively. The difference between the Company's expected Federal tax benefit calculated using a 34% tax rate and the Company's zero tax benefit for all years is primarily related to a full valuation allowance established against the Company's net operating loss carryforwards for 2008 and the tax effects of stock compensation under FAS 123R.

If certain substantial changes in the Company's ownership should occur, there would potentially be an annual limitation on the amount of the carryforwards, which could be utilized in a tax year. The Company has not performed a Section 382 change in control test to date. Until this test is performed, the Company cannot be certain of the use of the loss carryforwards.

6. Related Party Licenses and other Agreements and Contingencies

Colthurst, Edenland and Mr. Prendergast

During 1994, the Company entered into two license agreements and one research, development and option agreement as discussed in the following paragraphs.

Pursuant to a license agreement dated May 18, 1994 (Colthurst License Agreement) with related parties, Patrick T. Prendergast, a significant stockholder at the time, and with Colthurst Limited, a company controlled by Mr. Prendergast, the Company acquired the exclusive worldwide rights to Mr. Prendergast's patent rights, know-how and background technology relating to the treatment of human/animal immunodeficiency.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

The agreement was amended on August 11, 1995 to change the license fee payment terms as discussed below in paragraph four of this Note. Per the license agreement, the Company agreed to pay royalties on product revenues.

On August 25, 1994, the Company entered into a license agreement (Edenland License Agreement) with a related party, Edenland Inc., a company controlled by Mr. Prendergast, for the exclusive worldwide rights to Mr. Prendergast's patent rights, know-how and background technology related to the substance tradenamed HE317 and to any other pharmaceutical product that became subject to the license agreement under the research, development and option agreement discussed below. The agreement was amended on August 11, 1995 to change the license fee payment terms as discussed in the following paragraph. Per the Edenland License Agreement, the Company agreed to pay royalties on product revenues.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

Effective August 11, 1995, Edenland, Inc., Colthurst Limited and the Company entered into amendments concerning the license fee payment terms to the two agreements described above. Under this amendment, the Company agreed to pay a license fee by April 28, 1996 plus additional license fees within 24 months of April 1996. The balances of these fees were paid in full by May 1997. As consideration for entering into certain amendments, the Company issued 75,472 shares of the Company's common stock to Edenland, Inc. and Colthurst Limited.

Per the amended Colthurst License Agreement, a renewal annual license fee was payable commencing May 1998. The Company paid this fee in 1998 by issuing shares of its common stock and, in 1999, paid in cash.

In August 1994, the Company entered into a Research, Development and Option Agreement, with Edenland, Inc. and Mr. Prendergast. The agreement provided for the development of HE317 to a certain stage of development and granted the Company the right of first option on new products developed by Edenland, Inc. The agreement committed the Company to pay for certain development costs up to the amount of \$3.0 million with certain contingencies for funding. In October 1996, the Company and Edenland, Inc. entered into an amendment, which accelerated the date that the \$3.0 million payment for HE317 or other product development costs was to be made. The Company paid \$2.7 million during 1997 and the remaining \$300,000 in April 1998.

On January 20, 2000, Hollis-Eden reached a settlement regarding various disputes with Mr. Prendergast, Colthurst and Edenland. The parties entered into two new technology agreements, the Technology Assignment Agreement and the Sponsored Research and License Agreement.

The Technology Assignment Agreement (Assignment Agreement) replaced the Colthurst License Agreement. Pursuant to the Assignment Agreement, Mr. Prendergast and Colthurst assigned to Hollis-Eden ownership of all patents, patent applications and current or future improvements of the technology under the Colthurst License Agreement, including IMMUNITIN, Hollis-Eden's lead clinical compound at the time. The annual license fee of \$500,000 and the royalty obligations under the Colthurst License Agreement were eliminated. In consideration for the foregoing, Hollis-Eden agreed to issue to Colthurst 660,000 shares of Common Stock and a warrant to purchase an aggregate of 400,000 shares of Common Stock at \$25 per share. Only 132,000 of such shares of Common Stock were issued in 2000, with the remaining 528,000 shares to be issued over the next four years conditioned on continued compliance with the agreement and, in particular, satisfaction of the Conditions (as defined below). In addition, all of the shares under the warrant vest over four years conditioned on continued compliance with the agreement and, in particular, satisfaction of the Conditions (as defined below). The Sponsored Research and License Agreement replaced the Edenland License Agreement and the Research, Development and Option Agreement. Pursuant to the Sponsored Research and License Agreement, Edenland exclusively licensed to Hollis-Eden a number of compounds, together with all related patents and patent applications, and Hollis-Eden funded additional preclinical research projects conducted by Edenland. Hollis-Eden would also have exclusive license rights to all results of such research and would have royalty obligations to Edenland on sales of new products, if any, resulting from such research. None of the compounds licensed under the Sponsored Research and License Agreement have been developed by Hollis-Eden and, as described below, this agreement is now terminated.

As stated above, the issuance of the additional shares of Common Stock and the vesting of the warrant was dependent upon the satisfaction of certain conditions (the Conditions). In accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, these future events could not be determined at the date of the agreements (January 2000). Accordingly, the shares and warrants are accounted for as they vest or are issued. During 2000, the Company

recorded a research and development charge for \$1.9 million representing the fair value of the 132,000 shares issued under the Assignment Agreement.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

Because all of the Conditions were not satisfied, Hollis-Eden did not issue any additional shares to Colthurst and believed it had no obligation to issue any additional shares and that the warrant would not vest as to any shares of Common Stock.

After arbitration proceedings during 2004 and 2005, pursuant to which Colthurst sought more than \$25 million in damages for the non-issuance of the 528,000 shares of common stock and the warrant to purchase up to 400,000 shares of common stock, in February 2006 the parties agreed to a settlement and release of all issues in dispute between the parties. Under the settlement agreement, (1) the Company agreed to make a payment of \$3 million in cash and (2) the parties agreed to terminate the Sponsored Research and License Agreement between the Company and Edenland Inc. The \$3.0 million was accrued as an expense as of December 31, 2005. Under the settlement agreement, the Colthurst parties remain prohibited from conducting any further research, development or commercialization activities of any kind relating in any way to the technology (including IMMUNITIN) that was assigned to the Company under the Assignment Agreement.

Aeson Therapeutics

In October 2000, the Company acquired a 21% equity stake in Aeson Therapeutics Inc. (Aeson) and an exclusive worldwide sublicense to three issued patents in the area of adrenal steroids in exchange for \$2.0 million in cash and 208,672 shares of Common Stock valued at \$2 million. The cash and shares were expensed as in-process R&D during the fourth quarter of 2000. As part of the transaction, Aeson and its shareholders granted the Company an exclusive option to acquire the remainder of Aeson at a predetermined price.

In March 2002, the Company amended certain of its agreements with Aeson. Under the amendments, the Company paid Aeson \$1.2 million, which extended the initial date by which the Company could exercise its option to acquire the remainder of Aeson to September 30, 2002. Hollis-Eden also received additional equity securities as a result of its \$1.2 million payment. The \$1.2 million payment was expensed as in-process R&D. Hollis-Eden elected not to exercise the option to acquire the remainder of Aeson by September 30, 2002.

On June 7, 2006, the Company acquired substantially all of the assets of Aeson. As consideration for Aeson's assets, the Company agreed (i) to issue a total of 35,000 shares of common stock to Aeson at the closing of the acquisition and (ii) to issue to Aeson's stockholders up to a total of 165,000 additional shares of common stock if certain development milestones are achieved. The acquisition was expensed as in-process research and development. The Company has not achieved any of the development milestones.

Pharmadigm

In August 2002, we entered into a Sublicense Agreement with Pharmadigm, Inc. (currently known as Inflabloc Pharmaceuticals, Inc.). Under the agreement, we obtained exclusive worldwide rights to certain intellectual property of Pharmadigm and the University of Utah and we agreed to make aggregate payments of \$0.9 million in cash or in shares of our common stock, at our option, over the next year. This cost was expensed in

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

the third quarter of 2002. We elected to make such payments in equity and have issued a total of 168,921 shares of our common stock in complete satisfaction of this requirement (of which 118,921 shares were issued the quarter ended March 31, 2003). We may also make substantial additional milestone and royalty payments in cash to Pharmadigm if we meet specified development and commercialization milestones for products covered by the patents. To date, no such milestones have been met. The principal patents licensed under the agreement, originally licensed to Pharmadigm from the University of Utah, relate to inventions by Dr. Raymond Daynes and Dr. Barbara A. Areneo. Dr. Daynes served as a scientific consultant to Hollis-Eden from 1999 to mid-2003.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

Congressional Pharmaceutical

In February 2004, the Company acquired Congressional Pharmaceutical Corporation (CPC) and replaced CPC as the exclusive licensee to certain intellectual property rights held by the University of Chicago. These intellectual property rights consist of a series of patents and patent applications that relate to discoveries made by David J. Grdina, Ph.D., Professor of Radiation and Cellular Oncology at the University of Chicago. The patented technology covers a series of compounds that have the potential to protect against DNA mutations that can occur as a result of radiation injury or chemotherapy. In the acquisition the Company issued approximately 50,000 shares of common stock to the former stockholders of CPC valued at approximately \$650,000, in accordance with Emerging Issues Task Force No. 99-12. In addition, if the Company achieves certain development milestones, it will be required to issue additional shares of our common stock to the former stockholders of CPC. In the event all of the milestones are achieved, the total number of additional shares that the Company would be required to issue to the former stockholders of CPC is 275,000, more than half of which would be issued only upon FDA approval of CPC 's product. No such milestone has been met to date. Furthermore, upon regulatory approval and commercialization of products covered by the licensed intellectual property, the Company may be required to pay royalties to the former stockholders of CPC and the University of Chicago. Following the acquisition, Dr. Grdina agreed to an exclusive consulting arrangement with the Company in the fields of hematopoiesis and radiation and chemotherapy exposure. In March 2007, the Company terminated its consulting agreement with Dr. Grdina. In May 2007, the University of Chicago terminated the license agreement with the Company.

AFRRI Collaboration

The Company performed work on two task orders that were issued under a collaboration with the Armed Forces Radiobiology Research Institute (AFRRI). Under these task orders, the Company conducted radiation studies with a subcontractor. The task orders committed AFRRI to reimburse the Company for \$2.0 million in subcontractor fees. The reimbursement amounts from AFRRI were recorded in the same timeline as the subcontractor fees, resulting in no impact on the statement of operations. There was no activity during 2007 under the AFRRI collaboration. The Company terminated its collaborative research and development agreement with AFRRI effective August 12, 2007.

Study Funding Agreement

The Company has a Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT). The agreement commits CFFT to provide a total of \$1.7 million to be paid in seven tranches based on the Company 's completion of certain agreed-upon events. The agreement also contains a provision indicating that upon termination of this agreement by either party, CFFT shall pay the Company for all work performed through the date of termination, plus reasonable costs of bringing the study to an orderly close.

In return for this funding, the Company has agreed to pay CFFT a minimum royalty over a specified period following regulatory approval in the United States of America. Additional compensation is due to CFFT if net sales of this compound exceed a specified amount over a period of time.

Revenue is recognized under this agreement on a percentage of completion method for each distinct agreed-upon event. No revenue was recorded in 2008.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

7. Common Stock

Reverse Stock Splits

During February 1995, there was a 3-for-5 reverse stock split of the Company's common stock and in March 1996, a 1-for-2.65 reverse stock split of the Company's common stock. Both reverse stock splits have been retroactively reflected for all periods presented.

Common Stock Financings

In January 1996, the Company completed a \$367,522 round of debt financing with a group of private investors. These notes, with an 8% interest rate, were due on or before the earlier of (i) January 21, 1997 or (ii) the closing of a private or public offering of securities. During April 1996, the debt financing, plus accrued interest was converted into 164,962 shares of common stock at a price of \$2.25 per share. In April 1996, the Company privately issued 580,005 shares of the Company's common stock at an offering price of \$2.25 per share. Total proceeds from this offering aggregated \$1,234,499.

During May 1998, the Company completed a private financing totaling \$20.6 million in gross proceeds. The Company issued 1,329,201 shares of common stock, (of which 192,061 shares were subject to adjustment based on future average stock price (Adjustable Common Stock)), 4,000 shares of 5% Series A Convertible Preferred Stock and warrants to purchase 1,437,475 shares of common stock in the financing. The warrants entitled the holders to purchase up to a total of 1,437,475 shares of common stock at a price of \$17.00 per share.

The Convertible Preferred Stock had an initial conversion price of \$20.30 for the first seven months, after which it could be adjusted, either up or down, based on the future stock prices of the Company's common stock. The Convertible Preferred Stock was converted to common stock in January 1999 (See Note 8).

In January 1999, the Company completed two private placements of an aggregate of 1,367,868 shares of common stock at prices ranging from \$18.00 to \$18.50 per share. In connection with the private placements, the Company issued warrants to purchase an aggregate of 90,000 shares of the Company's common stock, with an exercise price of \$18.25 per share, as a finder's fee. The Company raised approximately \$25.0 million in gross proceeds.

During December 2001, the Company raised \$11.5 million in gross proceeds from the sale of 1.28 million shares of newly issued common stock in a private placement at a price of \$9.00 per share. The investors were a group of qualified institutional buyers and institutional accredited investors. The Company also issued warrants to purchase up to 128,000 shares of common stock having an exercise price of \$12.00 per share to

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

investors. As a finders fee, the Company issued to its placement agent two warrants for a total of 112,640 shares of common stock, one warrant with an exercise price of \$9.00 and the other with an exercise price of \$12.00.

On February 25, 2003, we completed a private placement in which we issued \$10.0 million aggregate principal amount of three-year convertible debentures (debentures), bearing interest at 7.5% per year, and warrants to purchase up to 701,760 shares of common stock. The debentures were convertible into common stock at a price of \$5.70 per share, which represented a discount from the price of our common stock on the commencement date. Also issued in connection with this private placement were warrants to purchase up to 350,880 shares of common stock which are exercisable at a price per share of \$6.17, subject to adjustment, and warrants to purchase up to 350,880 shares of common stock which are exercisable at a price per share of \$6.71, subject to adjustment. The warrants are exercisable until February 25, 2007.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

In connection with the issuance of the debentures and warrants, we recorded approximately \$3.5 million related to the beneficial conversion feature and approximately \$3.0 million for the detachable warrants on the debentures. The total amount of the deemed discount on the debentures as a result of the warrant issuance and the beneficial conversion feature amounts to \$6.5 million. The beneficial conversion feature and warrant value (deemed discount) were amortized over the term of the debentures and as conversion of the debentures occurred.

On June 20, 2003, convertible debentures with a face value of \$0.5 million were converted into 87,720 shares of our common stock leaving a \$9.5 million aggregate principle amount of convertible debentures outstanding. On August 11, 2003, the remaining aggregate principal amount of convertible debentures with a face value of \$9.5 million were converted into 1,666,680 shares of our common stock with a value of \$5.70 per share.

During June 2003, the Company completed a private placement of common stock and warrants, from which it received gross proceeds of \$14.7 million. In October 2003 the Company completed a public offering of an aggregate of 2,500,000 shares of common stock at a price of \$25.00 per share and received \$62.5 million in gross proceeds from this offering.

On June 1, 2005 the Company raised approximately \$10.0 million in gross proceeds from the sale of 1,333,333 shares of the Company's common stock at an exercise price of \$6.17 per share. Additionally, the Company issued a four-year warrant to purchase up to an additional 266,667 shares of common stock at an exercise price of \$10.00 per share. In connection with this transaction, the Company incurred approximately \$0.5 million in direct costs and recorded net proceeds of approximately \$9.5 million.

On February 6, 2006 the Company raised approximately \$26.0 million in gross proceeds from the sale of 4,000,000 shares of the Company's common stock at a price of \$6.50 per share. The direct costs related to this financing were \$1.7 million, resulting in net proceeds of \$24.3 million. Additionally, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants were not exercisable until six months following issuance.

On June 7, 2006 the Company issued 35,000 shares of the Company's common stock to Aeson Therapeutics, Inc. (Aeson) in connection with the purchase of substantially all of Aeson's assets, resulting in an expense of \$180,000. Upon certain events, the Company may be obligated to issue an additional 165,000 shares. The acquisition was expensed as in-process research and development. To date, the Company has not achieved any of the development milestones.

On November 13, 2006 the Company raised approximately \$26.0 million in gross proceeds from the sale of 4,000,000 shares of the Company's common stock at a price of \$6.50 per share. The direct costs related to this financing were \$1.6 million, resulting in net proceeds of \$24.4 million. Additionally, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants were not exercisable until six months following issuance.

8. Preferred Stock

During May 1998, as part of a private placement, the Company issued 4,000 shares of Convertible Preferred Stock for proceeds of \$4.0 million. The proceeds of the offering are included in the proceeds to the May 1998 financing described in Note 7, above.

During January 1999, the Company issued 346,127 shares of common stock in connection with the conversion of the Series A Convertible Preferred Stock and additional shares relating to the Adjustable Common

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

Stock. The Adjustable Common Stock was issued during the private placement of May 1998 and was subject to adjustment based on the future average stock price of the Company's common stock as described in Note 7. Upon conversion, all outstanding shares of Preferred stock and Adjustable Common stock were eliminated.

In November 1999, the Company adopted a Shareholders Rights Plan in which Preferred Stock purchase rights (Rights) were distributed as a dividend at the rate of one Right for each share of common stock held as of the close of business on November 29, 1999. Each right entitles stockholders to buy, upon certain events, one one-hundredth of a share of a new Series B junior participating preferred stock of the Company at an exercise price of \$100.00. The Rights are designed to guard against partial tender offers and other abusive tactics that might be used in an attempt to gain control of the Company or to deprive stockholders of their interest in the long-term value of the Company. The Rights are exercisable only if a person or group acquires 15% or more of the Company's common stock or announces a tender offer of which the consummation would result in ownership by a person or group of 15% or more of the Company's common stock. The Rights are redeemable for one cent per Right at the option of the Board of Directors prior to this event occurring. The Rights expire on November 14, 2009.

9. Stock Options and Restricted Stock

Stock Options

1997 Stock Option Plan

The 1997 Stock Option Plan (the 1997 Option Plan) was approved by the Company's stockholders in 1997. Under the 1997 Option Plan, shares of common stock have been reserved for issuance to employees, officers, directors, and consultants of the Company and provides for the grant of incentive and nonstatutory stock options. The Board of Directors determines terms of the stock option agreements, including vesting requirements. The exercise price of incentive stock options must equal at least the fair market value on the date of grant. The options expire not later than ten years from the date of the grant and generally are exercisable ratably over a three-year or four-year period beginning one-year from the date of the grant.

2005 Equity Incentive Plan

In June 2005, the Company's stockholders approved an amendment and restatement of the 1997 Option Plan to become the 2005 Equity Incentive Plan (the 2005 Equity Plan). Options granted under the 1997 Option Plan prior to its amendment and restatement will continue to be subject to the terms and conditions set forth in the agreements evidencing such options and the terms of the 1997 Option Plan except that the Board may elect to extend one or more of the features of the 2005 Equity Plan to stock awards granted under the 1997 Option Plan. The approval of the 2005 Equity Plan in June 2005 increased the number of shares reserved for issuance beyond those reserved for issuance under the 1997 Option Plan by 350,000 shares for a total of 5,500,000 reserved shares. The 2005 Equity Plan will allow the Company greater flexibility in designing equity incentives, including stock appreciation rights, stock purchase awards, restricted stock awards and restricted stock

unit awards. In December 2005, the Board of Directors amended the 2005 Equity Plan to reserve an additional 100,000 shares to be used only for the grant of stock awards to persons not previously employed by the Company, or following a bona fide period of non-employment, as an inducement material to those persons entering into employment with the Company with the meeting of the Rule 4350(i)(1)(A)(iv) of the NASDAQ Marketplace Rules, and to provide that any such inducement grants must be granted either by a majority of the Company's independent directors or a committee comprised of a majority of independent directors.

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)**

On March 18, 2006, the Board of Directors amended and restated the 2005 Equity Plan to reserve an additional 500,000 shares for issuance under the 2005 Equity Plan which was subsequently approved by the Company's stockholders in June 2006.

On March 30, 2007 the Board of Directors amended and restated the 2005 Equity Plan to reserve an additional 1,500,000 shares for issuance, for a total of 7,500,000 reserved shares and 100,000 inducement shares. The amendment was approved by the Company's stockholders in June 2007. The approval of the amendment allows the Company to continue to grant stock options and other awards at levels determined appropriate by our Board of Directors.

On March 28, 2008, the Board of Directors amended and restated the 2005 Equity Plan to reserve an additional 800,000 shares for issuance under the 2005 Equity Plan, which was subsequently approved by the Company's stockholders in June 2008. The following table summarizes stock option activity under the Plan and the 2005 Equity Plan for 1997 through 2008 (in thousands, except per share amounts):

		Price Per Share	
	Shares	Range	Weighted Average
1997			
Granted	518	\$ 6.75-8.70	\$ 7.13
Outstanding, December 31, 1997	518	\$ 6.75-8.70	\$ 7.13
1998			
Granted	341	13.25-16.75	14.52
Forfeited	100	8.70	8.70
Outstanding, December 31, 1998	759	\$ 6.75-16.75	\$ 10.24
1999			
Granted	776	10.56-16.63	12.70
Forfeited	61	14.06-14.63	14.63
Outstanding, December 31, 1999	1,474	\$ 6.75-16.75	\$ 11.36
2000			
Granted	774	6.50-15.06	8.18
Exercised	1	6.75	6.75
Forfeited	24	6.75-15.13	14.22
Outstanding, December 31, 2000	2,223	\$ 6.50-16.75	\$ 10.22
2001			
Granted	170	3.53-11.84	6.13
Forfeited	65	5.09-16.63	13.31

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Outstanding, December 31, 2001	2,328	\$ 3.53-16.75	\$ 9.80
2002			
Granted	696	5.15-10.10	9.48
Forfeited	55	5.13-13.13	8.17
Outstanding, December 31, 2002	2,969	\$ 3.53-16.75	\$ 10.98

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)**

	Shares	Price Per Share Range	Weighted Average
2003			
Granted	943	2.25-17.83	6.59
Exercised	85	4.50-13.13	11.25
Forfeited	66	4.00-16.75	12.17
Outstanding, December 31, 2003	3,761	\$ 2.25-17.83	\$ 8.88
2004			
Granted	596	8.54-15.20	13.69
Exercised	4	3.53-5.29	3.75
Forfeited	46	10.56-17.83	13.66
Outstanding, December 31, 2004	4,307	\$ 2.25-17.83	\$ 9.50
2005			
Granted	408	5.22-10.75	9.94
Exercised	13	3.53-6.68	5.67
Forfeited	56	5.29-10.47	8.06
Outstanding, December 31, 2005	4,646	\$ 2.25-17.83	\$ 9.57
2006			
Granted	965	4.43-7.08	5.67
Exercised	6	2.25-5.29	3.86
Forfeited	67	4.60-10.69	6.98
Outstanding, December 31, 2006	5,538	\$ 2.25-17.83	\$ 8.93
2007			
Granted	1,740	1.64-5.00	2.13
Exercised	9	2.25	2.25
Forfeited	1,607	2.25-16.75	8.29
Outstanding, December 31, 2007	5,662	\$ 1.64-17.83	\$ 7.02
2008			
Granted	1,067	0.65-16.63	2.07
Forfeited	442	1.26-16.75	10.58
Outstanding, December 31, 2008	6,287	\$ 0.65-17.83	\$ 5.93

Shares (in thousands)	Weighted- Average Exercise Price per	Weighted- Average Remaining Contractual	Aggregate Intrinsic Value (in thousands)
--------------------------	---	--	---

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

		Share	Term (in years)		
Outstanding, December 31, 2008	6,287	\$ 5.93	6.01	\$	0
Exercisable on December 31, 2008	4,290	\$ 7.53	4.78	\$	0

As of December 31, 2008, the total remaining shares of common stock available for grant under the 2005 Equity Plan is 1,941,153 (which includes 48,000 shares under the inducement pool).

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)*****2005 Non-Employee Directors' Equity Incentive Plan***

The 2005 Non-Employee Directors' Equity Incentive Plan (the "Non-Employee Directors Plan") was approved by the Company's stockholders in June 2006. Under the Non-Employee Directors Plan, 150,000 shares of common stock have been reserved for issuance to non-employee directors and provides for the grant of nonstatutory stock options, stock appreciation rights, stock purchase awards, restricted stock awards, restricted stock unit awards, and other forms of equity compensation. The Board of Directors determines terms of the stock awards, including vesting requirements. The exercise price of all options granted under the Non-Employee Directors Plan must equal at least the fair market value on the date of grant. The options expire not later than ten years from the date of the grant and generally are exercisable ratably during the option holder's continued service period.

On March 18, 2006, the Board of Directors amended and restated the 2005 Non-Employee Director's Equity Incentive Plan to reserve an additional 150,000 shares for issuance under the 2005 Non-Employee Director's Equity Incentive Plan which was subsequently approved by the Company's stockholders in June 2006.

On March 30, 2007 the Board of Directors amended and restated the 2005 Directors' Plan to reserve an additional 150,000 shares for issuance for a total of 450,000 shares reserved. The amendment was approved by the Company's stockholders in June 2007.

On March 28, 2008, the Board of Directors amended and restated the 2005 Non-Employee Director's Equity Incentive Plan to reserve an additional 150,000 shares for issuance under the 2005 Non-Employee Director's Equity Incentive Plan which was subsequently approved by the Company's stockholders in June 2008. The following table summarizes stock option activity under the Non-Employee Directors Plan for 2005-2008 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
2005			
Granted	30	\$ 10.75	\$ 10.75
Outstanding, December 31, 2005	30	\$ 10.75	\$ 10.75
2006			
Granted	253	\$ 5.43-11.75	\$ 7.55
Outstanding, December 31, 2006	283	\$ 5.43-11.75	\$ 7.89
2007			
Granted	75	\$ 2.14	\$ 2.14
Forfeited	30	\$ 5.43-6.19	\$ 5.81

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Outstanding, December 31, 2007	328	\$ 2.14-11.75	\$ 6.76
2008			
Granted	190	\$ 1.62-10.75	\$ 2.88
Forfeited	70	\$ 1.62-10.75	\$ 5.05
Outstanding, December 31, 2008	448	\$ 1.62-11.75	\$ 5.39

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)**

	Shares (in thousands)	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2008	448	\$ 5.39	6.65	\$ -0-
Exercisable on December 31, 2008	310	\$ 6.59	5.75	\$ -0-

As of December 31, 2008, the total remaining shares of common stock available for grant under the 2005 Non-Employee Directors' Equity Incentive Plan is 152,000 shares.

Non-Plan Options

During 1995 and 1996, the Company granted non-statutory stock options to purchase a total of 608,000 shares to directors, officers and consultants.

In February 1997, as part of an employment agreement, the Company granted a non-statutory stock option to an executive to purchase 2,400,000 shares of the Company's common stock at a price of \$5.00 per share, which vested ratably over a six-year period. The intrinsic value of the options was \$1,848,000. As a result, the Company recorded as deferred compensation a non-cash charge of \$1,848,000, which was being amortized ratably over the six-year vesting period. Through February 1999, the Company had amortized a total of \$641,333. In March 1999, the Company announced the resignation of this executive, at which time the Company and the executive agreed that the option would remain outstanding for a total of 1,200,000 shares, including the acceleration of vesting of 400,000 shares. This acceleration is considered to be a new grant of options and, as such, the Company took a one-time non-cash charge of \$4.9 million during the first quarter of 1999. No change was made to the terms of the option for the remaining 800,000 shares. On February 6, 2008, 400,000 of the options were forfeited.

In March 1999, the Company granted a non-statutory stock option to purchase 300,000 shares to an officer at an exercise price of \$16.63. The options were forfeited on December 31, 2008.

On June 17, 2004, the Company granted stock options to purchase a total of 80,000 shares of common stock of the Company, at an exercise price of \$11.75 per share, the fair market value of the date of grant, to two new directors. Options to purchase one-third of the total number of shares vest upon the first anniversary of the grant, and options to purchase the remaining shares vest in equal monthly installments over the following two years. At the direction of NASDAQ, with the agreement of the directors, these options were rescinded and cancelled in February 2006 and new options with the same terms were granted under the 2005 Non-Employee Directors' Equity Incentive Plan. No compensation was recognized upon issuance of new options as the exercise price exceeded the stock price at the date of the new grant. The options were forfeited in May 2007.

On June 24, 2004, the Company granted stock options to purchase 50,000 shares of common stock of the Company, at an exercise price of \$11.70 per share, the fair market value at the date of grant, to a new executive officer. Options to purchase one-fourth of the total number of shares vest upon the first anniversary of the grant, and options to purchase the remaining shares vest in equal monthly installments over the following three years.

On September 20, 2004, the Company granted stock options to purchase 40,000 shares of common stock of the Company, at an exercise price of \$10.79 per share, the fair market value at the date of grant, to a new executive officer. Options to purchase one-fourth of the total number of shares vest upon the first anniversary of the grant, and options to purchase the remaining shares vest in equal monthly installments over the following three years. The options were forfeited in November 2006.

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)**

On August 1, 2007, the Company granted stock options to purchase 150,000 shares of common stock of the Company, at an exercise price of \$1.66 per share, the fair market value at the date of grant, to a new executive officer. The options were forfeited in February 2008.

The following table summarizes stock option activity not pursuant to the Plan for 1995 through 2008 (in thousands, except per share amounts):

	Shares	Price Per Share Range	Weighted Average
1995			
Granted	38	\$ 2.65-7.95	\$ 4.64
Outstanding, December 31, 1995	38	\$ 2.65-7.95	\$ 4.64
1996			
Granted	570	2.25	2.25
Outstanding, December 31, 1996	608	\$ 2.25-7.95	\$ 2.40
1997			
Granted	2,400	5.00	5.00
Forfeited	50	2.25	2.25
Outstanding, December 31, 1997	2,958	\$ 2.25-7.95	\$ 4.51
1998			
Exercised	53	2.25-5.30	2.93
Forfeited	50	2.25	2.25
Outstanding, December 31, 1998	2,855	\$ 2.25-7.95	\$ 4.58
1999			
Granted	300	16.63	16.63
Exercised	10	7.95	7.95
Forfeited	1,220	2.25-5.00	4.95
Outstanding, December 31, 1999	1,925	\$ 2.25-16.63	\$ 6.16
Outstanding, December 31, 2000	1,925	\$ 2.25-16.63	\$ 6.16
2001			
Exercised	10	2.25	2.25
Outstanding, December 31, 2001	1,915	\$ 2.25-16.63	\$ 6.23
Outstanding, December 31, 2002	1,915	\$ 2.25-16.63	\$ 6.23

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

2003			
Forfeited	165	2.25	2.25
Outstanding, December 31, 2003	1,750	\$ 2.25-16.63	\$ 6.60
2004			
Granted	90	\$ 10.79-11.70	\$ 11.30
Outstanding, December 31, 2004	1,840	\$ 2.25-16.63	\$ 6.83

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

	Shares	Price Per Share	
		Range	Weighted Average
2005			
Granted	28	\$ 6.39-7.59	\$ 7.00
Exercised	22	2.25	2.25
Outstanding, December 31, 2005	1,846	\$ 2.25-16.63	\$ 6.89
2006			
Exercised	28	\$ 2.25	\$ 2.25
Forfeited	220	2.25-11.70	3.10
Outstanding, December 31, 2006	1,598	\$ 5.00-16.63	\$ 7.49
2007			
Granted	150	\$ 1.66	\$ 1.66
Forfeited	84	7.59-11.70	10.58
Outstanding, December 31, 2007	1,664	\$ 1.66-16.63	\$ 6.81
2008			
Forfeited	850	\$ 1.66-16.63	\$ 8.52
Outstanding, December 31, 2008	814	\$ 5.00-6.39	\$ 5.02

	Shares (in thousands)	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2008	814	\$ 5.02	0.23	\$ 0
Exercisable on December 31, 2008	811	\$ 5.02	0.21	\$ 0

For various price ranges, weighted average characteristics of outstanding stock options at December 31, 2008 were as follows:

Range of Exercise Prices	Outstanding options Remaining			Exercisable options	
	Shares	life (years)	Weighted average price	Shares	Weighted average price
\$ 0.65-\$ 1.66	2,296,850	8.50	\$ 1.64	738,180	\$ 1.64
\$ 1.67-\$ 5.29	1,772,950	3.20	\$ 4.44	1,531,860	\$ 4.59
\$ 5.30-\$ 7.43	1,527,755	5.20	\$ 5.99	1,202,657	\$ 6.10

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

\$ 7.44-\$14.97	1,832,431	3.60	\$	11.49	1,819,116	\$	11.49
\$15.00-\$17.83	119,500	1.74	\$	16.51	119,500	\$	16.51
Balance as of 12/31/2008	7,549,486	5.29	\$	5.80	5,411,313	\$	7.10

Options exercisable at December 31, 2008, 2007 and 2006 were 5,411,313, 5,138,358 and 5,836,911 at weighted average exercise prices of \$7.10, \$8.78 and \$8.94, respectively.

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)**

The weighted average, estimated fair values of employee stock options granted during the fiscal years ended December 31, 2008, 2007 and 2006 were \$1.02, \$1.14 and \$4.22 per share, respectively.

The total stock-based compensation expense included in our statement of operations for the fiscal years ended December 31, 2008, 2007 and 2006 was \$2.5 million, \$3.2 million and \$3.6 million, respectively. Of the \$2.5 million stock-based compensation expense in 2008, \$2.1 million relates to awards granted prior to January 1, 2008.

As of December 31, 2008, the unrecognized stock-based compensation expense related to non-vested options and restricted shares was approximately \$3.9 million which is expected to be recognized over a weighted average period of approximately 2.14 years. During the fiscal year ended December 31, 2008 the total intrinsic value of the stock options exercised was \$0. The Company issues new shares of common stock upon the exercise of stock options.

Cash proceeds and the intrinsic value related to stock options exercised during the fiscal years 2008, 2007 and 2006 to date, are provided in the following table (in thousands):

	Fiscal Years Ended December 31,		
	2008	2007	2006
Proceeds from stock options exercised	\$ 0	\$ 20	\$ 86
Tax benefit related to stock options exercised(1)	NA	NA	NA
Intrinsic value of stock options exercised(2)	\$ 0	\$ 28	\$ 145

- (1) SFAS 123R requires that the excess tax benefits received related to stock option exercises be presented as financing cash inflows. The Company currently does not receive a tax benefit related to the exercise of stock options due to the Company's net operating losses.
- (2) The intrinsic value of stock options exercised is the amount by which the market price of the stock on the date of exercise exceeded the market price of the stock on the date of grant.

Restricted Stock

The fair value of restricted stock is based on the trading price of the Company's common stock on the date of grant. We issued restricted stock for the first time during 2006 to certain employees. Restricted stock activity is as follows:

(Shares in thousands)

Shares

Weighted-
Average

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

		Grant Date Fair Value
Outstanding at beginning of year		
Granted	68	\$ 6.20
Forfeited	4	\$ 6.20
Outstanding December 31, 2006	64	\$ 6.20
Vested	22	\$ 6.20
Forfeited	12	\$ 6.20
Outstanding December 31, 2007	30	\$ 6.20
Vested	12	\$ 6.20
Outstanding December 31, 2008	18	\$ 6.20

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

The market price of the common stock on the date of the grant was initially recorded as deferred compensation within the stockholders' equity section of the Company's balance sheet and subsequently is being amortized over the 4-year vesting period. During the fiscal years ended December 31, 2008, 2007 and 2006 there was approximately \$85,700, \$90,000 and \$93,000 of compensation expense, respectively, was amortized and is included in general and administrative and research and development expense in the statement of operations.

10. Common Stock Purchase Warrants

Series A Warrants

During April 1996, in accordance with anti-dilution privileges triggered by an offering in March 1995, the Company issued 1,018,866 Series A Warrants to all stockholders of record as of March 1995 to purchase the same number of shares of common stock at a price of \$11.02 per share. The warrants expired January 2002, except for one warrant for 393,250 shares, which expired January 7, 2006.

IAC Management Warrants

During April 1994, the Company issued warrants, to existing shareholders and management, to purchase 160,000 units (the Units) at \$10.00 per Unit, each unit to be identical to the Units issued as part of its initial public offering. Each Unit consists of (i) one share of common stock, \$.01 par value per share and (ii) one Class A Warrant entitling the holder to purchase one share of common stock at a price of \$9.00 per share. All the warrants have expired.

Representatives Warrants

In connection with the Company's initial public offering, the Company issued warrants to the underwriters for 60,000 Units at an exercise price of \$11.00 per Unit and 24,000 Class B Warrants at an exercise price of \$5.775 per warrant and were exercisable until May 2000. Each Class B Warrant entitled the holder to purchase one Unit (i.e. one share of common stock and one Class A Warrant). The unexercised warrants have expired.

Investor Relations Warrant

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

During February 1998, as part of payment for services relating to investor relations, the Company issued a warrant to purchase 150,000 shares with an exercise price of \$14.75 per share and an expiration date of February 1999. The warrant was estimated to have a value of \$408,000, which was expensed in 1998. This warrant was exercised.

1998 Private Placement Warrants

In connection with the May 1998 private placement, the Company issued warrants to purchase 1,437,475 shares of common stock at an exercise price of \$17.00 per share. The warrants were exercisable until May 2001. Of the warrants issued, 157,000 were issued as finders fees, and 1,280,475 were issued to the private placement investors. These warrants have expired.

1999 Agent Warrants

In connection with the January 1999 private placement, the Company issued warrants as a finder's fee to purchase 90,000 shares of common stock at an exercise price of \$18.25 per share. The warrants expired in January 2002.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

1999 Consulting Warrant

During March 1999, the Company entered into a three-year agreement with a financial consulting organization affiliated with a director of the Company. The Company agreed to issue as compensation for services, a warrant to purchase 500,000 shares of common stock with an exercise price of \$20.50 per share and an expiration date of March 2002. The warrant was not subject to any vesting provisions. The warrant was estimated to have a value of approximately \$2.1 million, which was expensed as a non-cash charge during the first quarter of 1999. During 2001, the expiration date for this warrant was extended to March 2003.

During March 2003, the Company amended the consulting arrangement with the same financial organization affiliated with a director. The Company amended the warrant so that the warrant is now exercisable into an aggregate of 250,000 shares of common stock with an exercise price of \$10.00 per share and an expiration date of the earlier of March 12, 2006 or thirty days after the consulting agreement is terminated. The warrant expired without being exercised. A non-cash charge of approximately \$0.8 million was expensed. For accounting purposes, the original warrant was considered cancelled and a new warrant issued as a replacement. This warrant has expired.

2001 Consulting Warrants

During April 2001, the Company issued warrants to purchase 25,000 shares of common stock at an exercise price of \$3.09 per share. The warrants expired April 30, 2006. During July 2001, the Company issued warrants to purchase 25,000 shares of common stock at an exercise price of \$6.225 per share. These warrants were exercisable until July 31, 2006. These warrants, collectively, were issued for compensation for services and were estimated to have a combined value of approximately \$208,000, which was expensed as a non-cash charge. Approximately 15% of these warrants have been exercised.

During the fourth quarter of 2001, the Company issued three-year warrants to purchase 16,870 shares of common stock with exercise prices ranging from \$4.72 to \$10.10 per share. The warrants have no vesting period and were issued in lieu of cash for services. An estimated value for these warrants of approximately \$80,000 was expensed. The majority of these warrants have not been exercised. The unexercised warrants have expired.

2001 Private Placement Warrants

In connection with the December 2001 private placement, the Company issued warrants to purchase 128,000 shares of common stock to investors with an exercise price of \$12.00. Warrants to purchase 68,329 shares of our common stock were exercised and the remaining warrants expired December 11, 2003.

As a finders fee, the Company issued two warrants to the placement agent for a total of 112,640 shares of common stock. One warrant has an exercise price of \$9.00 per share and the other an exercise price of \$12.00 per share. The value ascribed to these warrants based on the Black-Scholes pricing model was \$1.5 million and was included as a charge to equity. These warrants to purchase 68,329 shares of our common stock were previously exercised and the remaining unexercised warrants expired in December 2006.

2002 Consulting Warrants

In March 2002, the Company agreed to issue a three-year warrant to a consultant, Dr. Joseph Hollis, to purchase up to 60,000 shares of common stock at an exercise price of \$11.00 per share for services rendered in 2002. Dr. Hollis is the brother of Richard B. Hollis. This warrant expired with 50,000 shares unexercised.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

During the fourth quarter of 2002, the Company issued a three-year warrant to purchase up to 10,000 shares of common stock at an exercise price of \$4.54 per share. The warrants were issued in lieu of cash for consulting services performed for the Company during 2002. The unexercised warrants have expired.

All of the 2002 warrants were valued at a total of \$247,000 using the Black-Scholes pricing model. The value of the warrants was expensed and is included in the 2002 operating expenses.

2003 Convertible Note and Warrants

On February 25, 2003, the Company completed a private placement in which the Company issued \$10.0 million aggregate principal amount of three-year convertible debentures (debentures), bearing interest at 7.5% per year, and warrants to purchase up to 701,760 shares of common stock. The debentures are convertible into common stock at a price of \$5.70 per share, which represented a discount from the price of common stock on the commencement date. Also issued in connection with this private placement were warrants to purchase up to 350,880 shares of common stock which are exercisable at a price per share of \$6.17, subject to adjustment, and warrants to purchase up to 350,880 shares of common stock which are exercisable at a price per share of \$6.71, subject to adjustment. Approximately half of these warrants have been exercised. The balance of these warrants expired February 2007.

In connection with the issuance of the debentures and warrants, the Company recorded approximately \$3.5 million related to the beneficial conversion feature and approximately \$3.0 million for the detachable warrants on the debentures. The total amount of the deemed discount on the debentures as a result of the warrant issuance and the beneficial conversion feature amounts to \$6.5 million. The beneficial conversion feature and warrant value (deemed discount) were amortized over the term of the debentures and as conversion of the debentures occurred.

The placement agent received a warrant to purchase 73,684 shares of common stock having an exercise price of \$5.99 per share. The value ascribed to this warrant based on the Black-Scholes pricing model was \$0.4 million and was expensed as a non-cash charge. This warrant expired in February 2008.

2003 Private Placement Warrants

In connection with the June 2003 private placement, the Company issued warrants to purchase 192,456 shares of common stock to investors with an exercise price of \$15.45 per share. Approximately 13,000 warrants have been exercised and the remaining warrants expired in June 2007.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

As a finders fee, the Company issued a warrant to the placement agent, for a total of 44,266 shares of common stock with an exercise price of \$13.22 per share. The value ascribed to this warrant based on the Black-Scholes pricing model was \$0.5 million and was charged to equity. This warrant expired in June 2008.

2004 Consulting Warrants

During 2004, the Company issued two two-year warrants to purchase up to a total of 12,000 shares of common stock at exercise prices of \$10.15 and \$11.75 per share. The warrants were issued for consulting services performed for the Company and expired during 2006.

The 2004 warrants were valued at a total of \$108,280 using the Black-Scholes pricing model. The value of the warrants is amortized according to the vesting period which approximates the period over which the services are performed. In 2004, \$102,860 was expensed and is included in the 2004 operating expenses. The additional \$5,420 was expensed in 2005, over the remaining vesting period.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

2005 Financing Warrants

In connection with the June 2005 subscription agreement with a single institutional investor, the Company issued a four-year warrant to purchase up to an additional 266,667 shares of common stock at an exercise price of \$10.00 per share. The value ascribed to this warrant based on the Black-Scholes pricing model was \$1.8 million and was charged to equity. This warrant has not been exercised.

2006 Financing Warrants

In connection with the February 2006 financing agreement with institutional investors, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants became exercisable six months following issuance, and none have been exercised.

In connection with the November 2006 financing agreement with institutional investors, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants will become exercisable six months following issuance, and none have been exercised.

2006 Consulting Warrants

During 2006, the Company issued two two-year warrants to purchase up to a total of 14,000 shares of the Company's common stock at exercise prices of \$6.20 and \$5.52 per share. The warrants were issued for consulting services performed for the Company. These warrants expired in September and December 2008.

The 2006 warrants were valued at a total of \$40,320 using the Black-Scholes pricing model. The value of the warrants was amortized according to the vesting period which approximated the period over which the services were performed.

In December 2006, the Company issued a consulting warrant to purchase up to a total of 50,000 shares of the Company's common stock at an exercise price of \$5.52. The warrant was issued for consulting services performed for the Company. The warrant was valued at a total of \$215,000 using the Black-Scholes pricing model. The warrant vested immediately and was expensed in 2006. The expense is included in the 2006 operating expenses. This warrant has a ten-year life and has not been exercised.

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)**

The following table summarizes stock warrant activity for 2005 through 2008 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
Outstanding, December 31, 2004	1,587	\$ 3.09-15.45	\$ 9.82
2005			
Issued	267	10.00	10.00
Exercised	42	6.17	6.17
Forfeited	160	4.54-11.00	9.66
Outstanding, December 31, 2005	1,652	\$ 3.09-15.45	\$ 9.96
2006			
Issued	1,664	5.52-8.75	8.63
Exercised	10	3.09-6.23	3.22
Forfeited	787	3.09-12.00	10.25
Outstanding, December 31, 2006	2,519	\$ 5.52-15.45	\$ 9.02
2007			
Issued			
Exercised			
Forfeited	470	6.17-15.45	9.91
Outstanding, December 31, 2007	2,049	\$ 5.52-13.22	\$ 8.81
2008			
Issued			
Exercised			
Forfeited	132	5.52-13.22	8.39
Outstanding, December 31, 2008	1,917	\$ 5.52-10.00	\$ 8.84

For various price ranges, the following table summarizes the weighted average prices of outstanding warrants as of December 31, 2008 (in thousands, except per share amounts):

Range of Exercise Prices	Outstanding Warrants		Exercisable Warrants	
	Shares	Weighted average price	Shares	Weighted average price
\$5.01-\$ 8.00	50	5.52	50	5.52

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

\$8.01-\$10.00	1,867		8.93	1,867		8.93
Balance as of 12/31/2008	1,917	\$	8.84	1,917	\$	8.84

There were no warrants issued in 2008 and 2007. The weighted average exercise price of warrants issued in the fiscal year 2006 was \$9.02. The weighted average fair value of warrants issued in the fiscal year 2006 was \$3.68.

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)****11. Employment Agreement**

Pursuant to an employment agreement between Hollis-Eden and Mr. Richard B. Hollis entered into in November 1996, as amended (the Hollis Employment Agreement), Mr. Hollis' annual base salary was increased to \$225,000 upon the consummation of the Merger, with bonuses, future salary increases and equity compensation as determined by the Hollis-Eden Pharmaceuticals Board of Directors. Effective January 1, 2008, Mr. Hollis' base salary was increased for 2008 from \$532,480 to \$553,779. If Mr. Hollis' employment is terminated without cause, for insufficient reason or pursuant to a change in control (as such terms are defined in the Hollis Employment Agreement), Mr. Hollis will receive as severance (i) an amount equal to five times his then current annual base salary plus five times the amount of the bonus awarded to him in the prior calendar year, (ii) immediate vesting of all unvested stock options of Hollis-Eden Pharmaceuticals (or the surviving corporation in a change in control, if applicable) held by him and (iii) continued benefits under all employee benefit plans and programs for a period of three years. All of such payments are to be made in one lump sum within 30 days of termination. If Mr. Hollis' employment is terminated with cause or if Mr. Hollis resigns other than for sufficient reason, Mr. Hollis' compensation and benefits will cease immediately and Mr. Hollis will not be entitled to severance benefits. Mr. Hollis was terminated for cause on March 18, 2009.

12. Leases

Rental expenses for principal leased facilities under non-cancelable operating leases were approximately \$1,395,600, \$1,323,800 and \$958,000 for 2008, 2007 and 2006 respectively. Future minimum payments for operating leases as of December 31, 2008 are as follows (in thousands):

	Operating Leases
2009	\$ 1,157
2010	13
2011	
2012	
Total minimum lease payments	\$ 1,170

13. Fair Value Measurement

We adopted SFAS 157 as of January 1, 2008, for financial instruments measured at fair value on a recurring basis. SFAS 157 defines the fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States and expands disclosures about fair value measurements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. SFAS 157 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1

measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;

Level 2, defined as inputs other than quoted prices in active markets that are directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

HOLLIS-EDEN PHARMACEUTICALS, Inc.**(A Development Stage Company)****Notes to Financial Statements (Continued)**

Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant value drivers are observable.

We measure certain financial instruments at fair value on a recurring basis. Financial assets measured at fair value on a recurring basis are as follows at December 31, 2008:

	Level 1	Level 2	Level 3	Total
	In Thousands			
Money Market funds included in cash and cash equivalents	\$ 23,964	\$ 0	\$ 0	\$ 23,964
Total	\$ 23,964	\$ 0	\$ 0	\$ 23,964

14. Supplementary Financial Data (Unaudited)**Interim Financial Information****(Unaudited)**

Quarterly and year-to-date computations of loss per share amounts are made independently. Therefore, the sum of the per share amounts for the quarter may not agree with the per share amounts for the year.

	March	June	Quarter September	December	Total Year
	(In thousands, except per share)				
Year Ended December 31, 2008					
R&D operating expenses	\$ 4,126	\$ 4,173	\$ 3,339	\$ 3,454	\$ 15,092
G&A operating expenses	1,484	1,400	1,128	1,013	5,025
Non-cash charges	553	665	598	674	2,490
Net loss	(5,748)	(5,987)	(4,855)	(4,975)	(21,565)
Net loss per share	(0.20)	(0.21)	(0.17)	(0.17)	(0.74)
Cash and cash equivalents	38,961	34,123	29,062	24,152	24,152
Year Ended December 31, 2007					
R&D operating expenses	\$ 4,287	\$ 4,324	\$ 4,278	\$ 4,185	\$ 17,074
G&A operating expenses	1,930	1,543	1,125	1,562	6,160
Non-cash charges	988	659	915	673	3,235
Net loss	(6,468)	(5,807)	(5,653)	(5,193)	(23,121)
Net loss per share	(0.22)	(0.20)	(0.20)	(0.18)	(0.80)

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Cash and cash equivalents	58,430	52,170	48,215	43,215	43,215
---------------------------	--------	--------	--------	--------	--------

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Hollis Eden Pharmaceuticals, Inc.

San Diego, California

We have audited the accompanying balance sheets of Hollis-Eden Pharmaceuticals Inc. (the Company) (a development stage company) as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2008 and for the period from inception (August 15, 1994) to December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Hollis-Eden Pharmaceuticals Inc. as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2008 and for the period from inception (August 15, 1994) to December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO Seidman, LLP

Costa Mesa, California

March 30, 2009

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A(T). Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Hollis-Eden's management, including our Interim Chief Executive Officer and Interim Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e) 15d-15(e). Based upon that evaluation, our Interim Chief Executive Officer and Interim Chief Financial Officer concluded that our disclosure controls and procedures are effective in enabling the Company to record, process, summarize and report information required to be included in the Company's periodic SEC filings within the required time period.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for Hollis-Eden. Hollis-Eden's internal control system was designed to provide reasonable assurance to Company management and board of directors regarding the preparation and fair presentation of published financial statements in accordance with accounting principles generally accepted in the United States (GAAP).

Management recognizes its responsibility for fostering a strong ethical climate so that the Company's affairs are conducted according to the highest standards of personal and corporate conduct.

The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded properly to allow for the preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and the Board of Directors of the Company;
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements; and
- provide reasonable assurance as to the detection of fraud.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changing conditions, effectiveness of internal control over financial reporting may vary over time. The Company's processes contain self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Management has assessed the effectiveness of Hollis-Eden's internal control over financial reporting as of December 31, 2008, based on the criteria for effective internal control described in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2008.

This annual report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in Hollis-Eden's internal controls over financial reporting that occurred during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART III
Item 10. Directors, Executive Officers and Corporate Governance

See the section entitled "Executive Officers and Senior Management" in Part I, Item 1 of this Annual Report on Form 10-K for information regarding executive officers and senior management.

The other information required by this Item 10 is set forth in Hollis-Eden's definitive Proxy Statement which is expected to be filed with the Commission pursuant to Regulation 14A in connection with the Hollis-Eden's 2009 Annual Meeting (the "Proxy Statement") not later than 120 days after the end of our fiscal year ended December 31, 2008. This information is set forth in the Proxy Statement under the heading "Election of Directors" and is incorporated herein by reference to the Proxy Statement.

Item 11. Executive Compensation

The information required by this Item 11 is set forth in the Proxy Statement under the heading "Executive Compensation" and is incorporated herein by reference to the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 is set forth in the Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management" and is incorporated by reference to the Proxy Statement.

The following table provides information as of December 31, 2008 with respect to all of our compensation plans under which we are authorized to issue equity securities of the company.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities in the first column)
Stock option equity compensation plans approved by security holders	6,783,049	\$ 5.90	2,093,153
Stock option equity compensation plans not approved by security holders	813,500	\$ 5.02	
Warrant equity compensation plans not approved by security holders	50,000	\$ 5.52	

Total	7,646,549	2,093,153
-------	-----------	-----------

The material features of each compensation plan or arrangement adopted without the approval of securities holders is included in Note 9 (Stock Options Non-Plan Options) and Note 10 (Common Stock Purchase Warrants) in our Notes To Financial Statements.

Unregistered Sales of Equity Securities and Use of Proceeds

We made no unregistered sales of securities or repurchases of our securities during the quarter ended December 31, 2008.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 is set forth in the Proxy Statement under the headings Certain Transaction and Independence of the Board of Directors and is incorporated by reference to the Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information concerning Principal Accountant Fees and Services is set forth in the Proxy Statement under the heading Ratification of Selection of Independent Auditors in the Proxy Statement which information is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents have been filed as part of this Annual Report on Form 10-K:

1. *Financial Statements*: The information required by this item is included in Item 8 of Part II of this report.
2. *Financial Statement Schedules*: Financial statement schedules required under the related instructions are not applicable for the three years ended December 31, 2008, and have therefore been omitted.
3. *Exhibits*: The exhibits listed in the Exhibit Index attached to this report are filed or incorporated by reference as part of this Annual Report.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

HOLLIS-EDEN PHARMACEUTICALS, INC.

By: /s/ JAMES M. FRINCKE
James M. Frincke,

Interim Chief Executive Officer

Date: March 30, 2009

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints ROBERT W. WEBER, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JAMES M. FRINCKE James M. Frincke	Interim Chief Executive Officer	March 30, 2009
/s/ ROBERT W. WEBER Robert W. Weber	Interim Chief Financial Officer / Chief Accounting Officer / Vice President Operations (Principal Financial Officer)	March 30, 2009
/s/ JEROME HAUER Jerome M. Hauer	Director	March 30, 2009
/s/ MARC R. SARNI Marc R. Sarni	Director	March 30, 2009
/s/ SALVATORE J. ZIZZA Salvatore J. Zizza	Director	March 30, 2009
	Director	March 30, 2009

Richard B. Hollis

INDEX TO EXHIBITS

Exhibit Number	Description of Document
*3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-4 (No. 333-18725), as amended (the Form S-4)).
*3.2	Bylaws of Registrant (incorporated by reference to Exhibit 3.2 to Registrant's Current Report on Form 8-K dated December 10, 2007).
*3.3	Certificate of Designation of Series B Junior Participating Preferred Stock (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K dated November 15, 1999).
*3.4	Certificates of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.4 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.)
*4.1	Rights Agreement dated as of November 15, 1999 among Registrant and American Stock Transfer and Trust Company (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K dated November 15, 1999).
* 10.1	Registrant's 1997 Incentive Stock Option Plan (the Option Plan) as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.2	Forms of Incentive Stock Options and Nonstatutory Stock Options under the Option Plan (incorporated by reference to Exhibit 10.5 to the Form S-4).
* 10.3	Form of Nonstatutory Stock Options outside the Option Plan (including Annex I, identifying the officers and directors who are holders of such options and their respective option amounts and exercise prices), (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.4	Employment Agreement by and between Registrant and Richard B. Hollis dated November 1, 1996 (incorporated by reference to Exhibit 10.6 to the Form S-4).
* 10.5	Employment Agreement by and between Registrant and Robert W. Weber dated March 16, 1996 (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998).
* 10.8	Nonstatutory Stock Option by and between Registrant and Terren S. Peizer effective as of February 6, 1997 (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.9	Separation and Mutual Release Agreement by and between Registrant and Terren S. Peizer effective as of February 25, 1999 (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999).
* 10.10	Nonstatutory Stock Option by and between Registrant and Richard B. Hollis effective as of January 1, 1999 (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
*10.16	Settlement and Mutual Release Agreement, dated January 20, 2000, among Registrant, Colthurst Limited, Edenland, Inc. and Patrick T. Prendergast (incorporated by reference to Exhibit 99.2 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.17	Technology Assignment Agreement, dated January 20, 2000, among Registrant, Colthurst Limited and Patrick T. Prendergast (incorporated by reference to Exhibit 99.3 to Registrant's Current Report on Form 8-K dated January 20, 2000).

Exhibit Number	Description of Document
*10.18	Common Stock and Warrant Agreement, dated January 20, 2000, among Registrant and Colthurst Limited (incorporated by reference to Exhibit 99.4 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.19	Warrant, dated January 20, 2000, issued to Colthurst Limited (incorporated by reference to Exhibit 99.5 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.20	Indemnification Agreement among Registrant and Executive Officers and Directors (incorporated by reference to Exhibit 10.17 to Registrant's Registration Statement on Form S-1 (No. 333-69454).
*10.26	Sublease dated December 19, 2001 between Cooley Godward LLP and Registrant (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001).
*10.27	Securities Purchase Agreement, dated as of February 25, 2003, by and between Hollis-Eden Pharmaceuticals, Inc. and the purchasers identified therein (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.28	Form of 7.5% Convertible Debenture issued to the purchasers listed on Schedule I attached thereto on February 25, 2003 (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.29	Form of Stock Purchase Warrant issued to purchasers listed on Schedule I attached thereto on February 25, 2003 (incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.30	Registration Rights Agreement, dated February 25, 2003, by and between Hollis-Eden Pharmaceuticals, Inc. and the purchasers identified therein (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.31	Warrant, dated February 25, 2003, issued to SG Cowen Securities Corporation (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.34	Warrant issued to SG Cowen Securities Corporation on June 19, 2003 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-3 (No. 333-106835)).
*#10.35	Study Funding Agreement, dated as of June 17, 2003, between the Registrant and Cystic Fibrosis Foundation Therapeutics, Inc (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003).
*10.37	Amended 401(k) Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003).
*10.38	First Amendment to Sublease dated December 19, 2001 between Cooley Godward LLP and Registrant (incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004).
*10.39	Form of Common Stock Purchase Warrant issued on June 1, 2005 (incorporated by reference to Exhibit 10.41 to the Registrant's Current Report on Form 8-K dated June 2, 2005).
*#10.40	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant entered into on December 3, 2003 (incorporated by reference to Exhibit 10.42 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).

Exhibit Number	Description of Document
*#10.41	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant entered into on February 17, 2004 (incorporated by reference to Exhibit 10.43 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.42	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated July 12, 2004 (incorporated by reference to Exhibit 10.44 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.43	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated October 19, 2004 (incorporated by reference to Exhibit 10.45 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.44	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated January 6, 2005 (incorporated by reference to Exhibit 10.46 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.45	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated May 16, 2005 (incorporated by reference to Exhibit 10.47 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
* 10.46	2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.47	Form of Option Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.48	Form of Restricted Stock Award Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.49	Form of Restricted Stock Unit Award Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.50	2005 Non-Employee Directors' Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.6 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.51	Form of Option Agreement for use under 2005 Non-Employee Directors' Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
*#10.52	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated November 30, 2005 (incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005).
*10.53	Form of Stock Purchase Agreement dated as of February 2, 2006 (incorporated by reference to Exhibit 10.48 to Registrant's Current Report on Form 8-K dated February 2, 2006) (the February 2006 Purchase Agreement).

Exhibit Number	Description of Document
*10.54	Form of Stock Purchase Warrant, issued pursuant to the February 2006 Purchase Agreement (incorporated by reference to the Current Report on Form 8-K dated February 2, 2006).
*10.55	Form of Stock Purchase Agreement dated as of November 7, 2006 (incorporated by reference to Exhibit 10.49 to Registrant's Current Report on Form 8-K dated November 7, 2006) (the November 2006 Purchase Agreement).
*10.56	Form of Common Stock Purchase Warrant, issued pursuant to the November 2006 Purchase Agreement (incorporated by reference to Exhibit 10.48 to Registrant's Current Report on Form 8-K dated November 7, 2006).
#10.58	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated December 11, 2006 (incorporated by reference to Exhibit 10.58 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2006).
* 10.60	Amendment to Employment Agreement dated as of December 7, 2007 between the Registrant and Richard B. Hollis (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K Dated December 10, 2007).
* 10.61	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated June 12, 2008 (incorporated by reference to Exhibit 10.61 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008).
23.1	Consent of BDO Seidman, LLP.
31.1	Rule 13a-14(a)/15d-14(a) Certification of James M. Frincke.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Robert W. Weber.
32.1	Section 1350 Certifications of James M. Frincke and Robert W. Weber.

* Previously filed.

Management contract or compensatory plan, contract or arrangement to be filed as an exhibit pursuant to Item 14(c) of Form 10-K.

Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.